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No.

IN THE

Supreme Court Of The United States

OCTOBER TERM, 1988

9/1 KG CONTAINERS, MORE OR LESS,
OF AN ARTICLE OF DRUG FOR VETERINARY USE,
AND SCHUYLER LABORATORIES, INC.,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

PETITION FOR WRIT OF CERTIORARI

JAMES R. PHELPS
(Counsel of Record)
ROBERT A. DORMER
HYMAN, PHELPS & MCNAMARA, P.C.
1120 G Street, N.W.
Washington, D.C. 20005
(202) 737-5600

Attorneys for Petitioners

Balmar Legal Publishing Division, Washington, DC 20005, (202) 659-3610

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QUESTIONS PRESENTED FOR REVIEW

1. Whether the Food and Drug Administration ("FDA") is empowered to control the manner in which veterinarians use medicines to treat their patients.

2. Whether bulk drug ingredients intended to be compounded by veterinarians solely in the course of their professional practices can be exempt from the statutory requirement to bear "adequate directions for use" under FDA's bulk drug regulation, 21 C.F.R. §201.122 (1988), or whether such drugs are unapproved "new animal drugs" and therefore may not be purchased by veterinarians until a new animal drug application has been approved by FDA for each use that the veterinarian will make of the drug.

LIST OF ALL PARTIES TO THE PROCEEDING

All parties in the proceeding appear in the caption of the case. Schuyler Laboratories, Inc., is an independent company and has no parent company, subsidiary or affiliate. In addition to the parties to the proceeding, the following were *amici curiae* in the Seventh Circuit: the American Feed Industry Association, a national trade association representing manufacturers and distributors of animal feeds and animal drugs; the American Food Animal Veterinary Medical Association, an association of food animal veterinarians; and the Animal Health Institute, a national trade association representing manufacturers and distributors of animal drugs.

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PETITION FOR WRIT OF CERTIORARI

Petitioners respectfully seek a writ of certiorari to review the opinion and order of the United States Court of Appeals for the Seventh Circuit ("Seventh Circuit").

OPINION BELOW

The opinion of the Seventh Circuit has not yet been reported; it is reproduced in the appendix ("App."). *United States v. 9/1 Kg Containers*, No. 88-1233 (7th Cir. July 27, 1988). App. 1a. The district court's decision is reported at 674 F. Supp. 1344 (C.D. Ill. 1987). App. 11a.

JURISDICTION

The judgment of the Seventh Circuit was entered on July 27, 1988. App. 25a. A petition for rehearing was denied on September 6, 1988. App. 26a. On September 30, 1988, the Seventh Circuit stayed the issuance of its mandate until October 12, 1988. App. 32a. The Seventh Circuit's order provides that its Stay will continue until final disposition of the petition if by October 12,

1988, a petition for a writ of certiorari is filed. *Id.* Jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

STATUTES AND REGULATIONS INVOLVED

This case chiefly involves the Federal Food, Drug, and Cosmetic Act ("FDC Act") §§201(w), 502(f) and 512(a)-(b), 21 U.S.C. §§321(w), 352(f), and 360b(a)-(b), and Title 21 of the Code of Federal Regulations, especially 21 C.F.R. §201.122. These are reproduced in the appendix. App. 27a.

STATEMENT OF THE CASE

The government seeks condemnation of bulk drugs that are intended solely for use by veterinarians to treat animals in the course of their licensed practices. The drugs, owned by petitioner Schuyler Laboratories, Inc. ("Schuyler"), were seized and remain in custody.

The purity, identity and proper strength of the drugs are not challenged and most are common, well-known products that have been used for years. Their value exceeds $200,000.00.

1. Statutory And Regulatory Framework

The FDC Act and two other statutes dealing specifically with biologic drugs[1] establish a comprehensive system for regulating drugs intended for both animal and human use, and those who manufacture such drugs for commercial purposes. Drugs that are adulterated or misbranded are subject to seizure, 21 U.S.C. §334 (1982), and persons who violate the law may be enjoined, 21 U.S.C. §332 (1982), or criminally prosecuted, 21 U.S.C. §§331, 333 (1982). Drug manufacturers are required to register annually with the FDA, 21 U.S.C. §§360(b) and (c) (1982), and must also list with FDA on a semi-annual basis all drugs they have distributed commercially, 21 U.S.C. §360(j) (1982). Drug manufacturers are also subject to extensive recordkeeping requirements, 21 U.S.C.

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[1] A biologic animal drug is a serum, vaccine, toxin or antitoxin that is intended for use in the treatment of domestic animals. 21 U.S.C. §151 (1982 & Supp. IV 1987). Animal biologics are approved by the United States Department of Agriculture under the Virus-Serum-Toxin Act, 21 U.S.C. §§151-159 (1982 & Supp. IV 1987), and human biologics are approved by FDA under the Public Health Service Act, 42 U.S.C. §262 (1982). As their name suggests, biologic drugs are products of biologic origin as opposed to drugs that are chemicals.

§351(a)(2)(B) (1982) and 21 C.F.R. Part 211 (1988), and FDA may inspect facilities in which drugs are manufactured or held, 21 U.S.C. §374 (1982).

The FDC Act has from the beginning treated commercial drug producers and practitioners differently. Congress has broadly excluded veterinarians and other practitioners from the requirements it has imposed on drug manufacturers. Practitioners are exempt from the registration requirement of the FDC Act when they "manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice." 21 U.S.C. §360(g)(2) (1982). Similarly, FDA has no authority to inspect the "records, files, papers, processes, and controls" of veterinarians and other practitioners who compound drugs for use in their practices. 21 U.S.C. §374(a)(1) and (a)(2)(B) (1982).

Certain drugs, known as "new drugs" or "new animal drugs," are subject to prior approval by FDA before they may be marketed. Drugs that are not "new" *are* nevertheless subject to all the other controls provided for in the statute. The FDC Act defines a "new animal drug" in part as one which is intended for use in animals other than man

> (1)the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience ... as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof ... or ...
>
> (3)which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof ....

21 U.S.C. §321(w) (1982).

> A "new animal drug" shall be deemed to be unsafe unless:
>
> (A)there is in effect an approval of an application filed pursuant to subsection (b) of this section [a new animal drug application or "NADA"] with respect to such use or intended use of such drug [and]
>
> (B)such drug, its labeling, and such use conform to such approved application ....

21 U.S.C. §360b(a)(1) (1982). An unapproved new animal drug is deemed "adulterated" and therefore subject to seizure. 21 U.S.C. §§351(a)(5) and 334 (1982).

The FDC Act requires that drugs, including biologic drugs, bear "adequate directions for use" unless they are exempted. 21 U.S.C. §352(f)(1) (1982). A proviso to section 352(f) states that where adequate directions for use are "not necessary for the protection of the public health, the Secretary [by delegation, FDA] shall promulgate regulations exempting such drug ... from such requirement." FDA has published a series of exempting regulations. 21 C.F.R. §§201.100-201.129 (1988).

The exemption at issue in this case is 21 C.F.R. §201.122 which provides:

> A drug in a bulk package, except tablets, capsules, or other dosage unit forms, intended for processing, repacking, or use in the manufacture of another drug shall be exempt from section 502(f)(1) of the Act if its label bears the statement "Caution: For manufacturing, processing, or repacking" .... But the exemption shall not apply to a substance intended for use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:
>
> (a)an approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder by persons named in the application ....

FDA regulates commercial drug manufacturers closely. In this case, the issue is whether medicines prepared and used by practitioners, who have stood outside the commercial drug approval system, may now be regulated in the same manner as those produced by commercial drug manufacturers.

2. Proceedings Below

The complaint[2] alleged that the seized goods were misbranded under 21 U.S.C. §352(f)(1) because they failed to bear "adequate directions for use." FDA asserted that the seized

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[2] Jurisdiction in the district court was invoked under 28 U.S.C. §1345 and 21 U.S.C. §334.

materials became unapproved "new animal drugs" when they were compounded into medicines by veterinarians and that therefore they cannot be exempt from the labeling requirement when shipped in bulk to veterinarians. The district court agreed with Schuyler that the bulk materials were not misbranded when sold to veterinarians and labeled "for manufacturing, processing, or repacking" in accordance with the FDA regulation exempting bulk products from the adequate directions for use requirement, 21 C.F.R. §201.122.[3] App. 23a.

The district court's opinion proceeded from a finding that the Congress had not intended that FDA should exercise authority over veterinarians in their medical decisions concerning drug therapy.[4] App. 19a. The professional use of veterinary medicines is not lawfully regulated under the "new drug" provisions, which would require prior approval for each and every patient treatment. App. 21a. The district court noted that the interpretation of the statute urged by FDA would "establish for the first time that it [FDA] is empowered to control an integral part of veterinary practice [*i.e.*, the prescribing and compounding of veterinary drugs]." App. 22a. The district court held that "Congress has *never* attempted to handcuff veterinarians in such a way and neither will this Court." App. 23a.

The reversal by the Seventh Circuit was based upon an entirely different reading of the legislative history of the FDC Act. App. 5a. The Seventh Circuit read the FDC Act to leave only matters of medical licensure and discipline to the states, and to give FDA control of the drug treatment choices and therapies of all medical practitioners. *Id.* In *dictum* the Seventh Circuit stated its view that practitioners were not sufficiently knowledgeable to use

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[3] FDA also contended that five lots of bulk antibiotics were adulterated because, as a matter of law, they were specifically named in the FDC Act as "new animal drugs," which required but did not have FDA approval. 21 U.S.C. §321(w)(3) (1982). The district court ruled they are not unapproved new drugs, App. 24a, and the Seventh Circuit did not reach this issue, App. 2a.

[4] In an injunction action based on the same legal issue in the District of New Jersey, the district court reached the same conclusion. *United States v. Algon Chemical, Inc.*, No. 87-1820 (D. N.J. April 12, 1988), *appeal docketed*, No. 88-5478 (3d Cir. June 17, 1988). App. 34a.

drugs safely without FDA supervision, and that tort relief against those practitioners who made mistakes would be insufficient to pay for injuries that might result (and inferentially that commercial houses would be able to pay or would be more responsible). App. 6a.

3. The Deleterious Effects of FDA's Proposed Interpretation Are Uncontested

The Seventh Circuit took it "as given that for significant diseases there are no effective FDA-approved drugs." App. 1a. This language and the examples cited by the court do not adequately describe the undisputed and unmitigated disaster that would occur if the Seventh Circuit opinion is the law; plainly more is involved than that "[m]any veterinarians find this state of affairs deplorable." App. 2a.

The record documents fully the practical consequences of permitting the control FDA contemplates. FDA did not attempt to controvert the following facts.

Like all practitioners of the healing arts, veterinarians must be able to prescribe and compound drugs for their patients.[5] Each of the healing professions, veterinary medicine included, is an art. Diseases and animals do not react to medicines with mechanical precision.[6] The efficacy of medicines will vary widely with individual animals and with diseases; a drug that is effective in one geographic area might simply not be as effective elsewhere for the same disease.[7]

The Seventh Circuit decision may have devastating consequences for the animals that provide the basics of the American food supply.[8] Acute mastitis, a disease that can destroy dairy *herds* within hours, cannot be treated effectively with FDA-approved

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[5] *See, e.g.*, Clack Statement at ¶¶3, 4, and 7, Supplemental Appendix of Appellees filed in the Seventh Circuit ("Appellees' S.A.") at 22-24.

[6] Clack Statement at ¶7, Appellees' S.A. at 23-24; Crouch Statement at ¶6, Appellees' S.A. at 28-29.

[7] *Id.*

[8] Clack Statement at ¶8 and attachment, Appellees' S.A. at 24, 26; VanDamme Statement at ¶¶5-7, Appellees' S.A. at 37-38.

remedies.[9] Nor can veterinarians treat the highly contagious respiratory infections that will kill an estimated 75% to 80% of affected calves unless they can compound effective medications.[10] Shipping fever and salmonella infections in feedlot cattle cannot be treated effectively with FDA-approved drugs.[11] There is no FDA-approved anesthetic that can be used in the field to do general surgery on food animals.[12] (Can FDA *really* intend that veterinarians engage in such an inhumane practice as performing surgery without an anesthetic?) There are no FDA-approved medicines for most of the diseases that afflict economically important nonfood species such as mink and fox.[13]

ARGUMENT

I. THE SEVENTH CIRCUIT'S INTERPRETATION OF THE FDC ACT RAISES IMPORTANT QUESTIONS REGARDING THE ADMINISTRATION OF THAT LAW

This case merits Supreme Court review. For the first time since the enactment of the basic Act fifty years ago, a court has ruled that a vital aspect of the practice of the healing arts, patient drug therapy, is directly within the authority of the Food and Drug Administration. Specifically, the Seventh Circuit has ruled that the agency may exert prior approval authority over each and every medicine used on patients by a veterinarian in his practice. The sweep of the opinion is such that it covers any medical practitioner, including physicians, who use drug therapy.

The effect of the ruling is to make it unlawful for veterinarians to use medicines in their practices until and unless a

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[9] VanDamme Statement at ¶7, Appellees' S.A. at 37-38; *9/1 Kg Containers*, App. 2a.

[10] VanDamme Statement at ¶6, Appellees' S.A. at 37. A major reason for the ineffectiveness of approved drugs where they exist is that the FDA-approved use of these drugs by laymen has led to resistance. Clack Statement at ¶6, Appellees' S.A. at 23.

[11] Skiles Statement at ¶¶4-5, Appellees' S.A. at 31-32; *9/1 Kg Containers*, App. 2a.

[12] Clack Statement at ¶8, Appellees' S.A. at 24; *9/1 Kg Containers*, App. 2a.

[13] Westlake Statement at ¶7, Appellees' S.A. at 41-42; *9/1 Kg Containers*, App. 2a.

commercial interest has seen fit to secure approval of a drug for the specific disease and the species that is affected by the disease. Even the use of an approved drug for an unapproved purpose is unlawful under the Seventh Circuit's decision. But veterinarians and other health care professionals cannot use the new drug approval system at the agency; it is geared to commercial enterprises. App. 8a.

The decision thus gives effect to a regulatory scheme that the director of FDA's Center for Veterinary Medicine acknowledges is inconsistent with the ethical practice of veterinary medicine. Appellees' S.A. at 69-71. The undisputed record thus establishes that veterinarians must disobey the law to prevent a health catastrophe.

This is clearly an instance when a "federal court of appeals has decided an important question of federal law which has not been, but should be, settled by this Court." Sup. Ct. R. 17.1(c). No court decision has ever before interpreted the FDC Act to permit the government to exert such complete control over the way practitioners treat their patients. The Seventh Circuit's ruling would create considerable change in the way FDA regulates under the FDC Act (the Seventh Circuit's opinion noted the vulnerability of "thousands of individual veterinarians" to prosecution, App. 2a), and would increase exposure to civil liability for those practitioners who exercised proper medical judgment to prescribe beyond FDA-approved labeling. The ruling affects health care for human beings and animals, and also the nation's food supply. The need for this Court to settle the matter is apparent.

II. THE SEVENTH CIRCUIT'S DECISION RESTS ON A NOVEL AND INCORRECT INTERPRETATION OF THE FDC ACT

A. The FDC Act Was Not Intended To Regulate The Practice of Medicine

Neither the language nor the legislative history of the FDC Act supports a finding that FDA must give prior approval to medicines compounded by veterinarians. The legislative history

establishes beyond any possible doubt that the FDC Act was *not* intended to regulate the practice of any of the healing arts.

The Seventh Circuit held that the district court erred in its conclusion that "it was not the purpose of the Act to involve the agency in the practice of the healing arts," and held that the Act allows FDA to make the ultimate determination for any drug, even drugs used by licensed practitioners to treat individual patients, as to whether such drug is "ineffective or dangerous." App. 5a. The Seventh Circuit reached its conclusion based on its finding that the FDC Act was intended "to regulate drugs," this Court's ruling in *United States v. Rutherford*, 442 U.S. 544 (1979), and on one phrase in the legislative history of the basic 1938 Act. The phrase appeared in a 1935 Senate Report and stated that the Act was "not intended as a medical practices act and [would] not interfere with the practice of the healing art *by chiropractors and others*." *Id.*[14] According to the Seventh Circuit, this passage "makes the point" that Congress intended only to avoid interference with practitioners who do not use drugs in their practices. *Id.*

In the fifty years since the FDC Act became law, courts, FDA, and legal experts have on other occasions reviewed the legislative history of the Act, and all of them have reached a different conclusion than that reached by the Seventh Circuit. An analysis of the legislative history of the 1938 FDC Act shows that the Seventh Circuit's opinion has overlooked portions of that history that render its analysis incorrect.[15]

The proposed legislation which ultimately became the 1938 FDC Act was first introduced in 1933, "and was immediately ques-

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[14] Quoting S. Rep. No. 361, 74th Cong., 1st Sess. 3 (1935), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. III at 660 (emphasis added by the Seventh Circuit).

[15] It is curious that the Seventh Circuit, after saying that it was required to defer to an agency's interpretation of its governing statutes, App. 5a, used this language from the legislative history to support a statutory interpretation that FDA never made. In the court below FDA had contended that the 1968 Animal Drug Amendments, not the 1938 FDC Act, gave it the authority to require approval of compounding by veterinarians. *See* discussion of the 1968 Animal Drug Amendments, *infra* at 15.

tioned by parts of the medical profession as an attack upon the prerogatives of the physician." Hutt, *Regulation of the Practice of Medicine Under the Pure Food and Drug Laws*, 33 Assoc. of Food and Drug Officials Q. Bull. 8 (1969). As a result of this concern, the definition of the term "drug" was amended to add the words, "and not to regulate the legalized practice of the healing art." S. 2800, 73rd Cong., 2d Sess. 2 (1934), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. II at 671.

As Senator Copeland, the bill's sponsor, explained:

> There was a feeling on the part of certain divisions of the medical profession that there was an attack upon the prerogatives of the doctor, particularly of the chiropractors .... [T]his bill makes certain that the medical practitioner shall not be interfered with in his practice.

78 Cong. Rec. S2728-29 (daily ed. February 19, 1934), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. I at 800.

Senator Copeland's statement, combined with the amended language of the Act to which he referred, demonstrates that when Congress precluded regulation of the practice of medicine it did not mean merely those practices that did not entail the use of drugs. Had Congress intended to avoid only the regulation of chiropractors, the amended language would have reflected this intent. The broad language used by Congress, and Senator Copeland's concluding statement that "this bill makes certain that the medical practitioner shall not be interfered with in his practice," demonstrate the *certain* intent of Congress to avoid regulating the treatment decisions of all practitioners of the healing arts, including those who use drugs.[16]

Any doubt as to Congress' intent to avoid regulation of the prescriptions of licensed practitioners was removed in subsequent

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[16] The term "medical profession" was defined in the 1934 version of the Act to mean "the professions of medicine, pharmacology, dentistry [and] veterinary medicine." S. 2800, 73rd Cong., 2d Sess. 2 (193-), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. II at 671.

debate of the Act. In 1935 Senator Lewis, showing his desire to avoid regulating the medicines used by licensed practitioners, attempted to exclude from the term "drug" any "medicine *prepared* and dispensed by a physician in the course of his professional practice." 79 Cong. Rec. S5019 (daily ed. April 5, 1935), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. IV at 57 (emphasis added). However, Senator Copeland assured Senator Lewis that the word "drug" was not intended to apply to the preparations of a physician dispensed in the course of his practice:

> *Mr. Copeland.* The matter the Senator from Illinois has in mind is whether or not this measure interferes at all with a written prescription of a doctor.
>
> *Mr. Lewis.* The word "drug" is not intended to apply to preparations dispensed by a doctor himself in the course of his professional practice.
>
> *Mr. Copeland.* There is nothing in the bill which would interfere at all with the ordinary legal practice of the profession.

Id.

This debate, which has none of the qualifications that the Seventh Circuit read into the phrase it relied upon, shows conclusively that Congress intended to refrain from any regulation that would impinge on the treatment decisions of licensed practitioners, decisions that Congress recognized are tailored to the patients' needs, *including* what medications work best for that individual. The Seventh Circuit overlooked this vital commentary.

A former chief counsel of FDA concluded in his analysis of the legislative history of the 1938 Act:

> Through the six years of legislative history the proposed legislation contained the affirmative requirement that every drug must bear adequate directions for use. Not only does the legislative history fail to show a Congressional intent that this be used to restrict the conditions for which physicians might prescribe drugs, but it flatly contradicts any such interpretation.

Hutt at 9.[17] As recently as a few years ago, FDA was arguing that the intent of Congress was not "to limit a physician's ability to treat his patients." *Chaney v. Heckler*, 718 F.2d. 1174, 1179 n.13 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985). The Seventh Circuit ruling contradicts this.

B. The Drug Amendments Act Of 1962 Specifically Exempted Practitioners From New Requirements Imposed On Commercial Enterprises

Actions of Congress subsequent to the passage of the basic FDC Act have been entirely consistent with what FDA in 1983 called the "commonly recognized exemption to the Act's broad and protective coverage: the 'practice-of-medicine' exemption." *Chaney*, 718 F.2d at 1179. The Drug Amendments Act of 1962 made comprehensive changes in the FDC Act and greatly increased FDA's ability to regulate commerce in pharmaceuticals intended for both human and veterinary use. Pub. L. No. 87-781, 76 Stat. 780 (1962), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIII at 228. Prior to 1962, "new drugs" had to be approved on the basis of safety alone. The 1962 Amendments added the requirement that a manufacturer demonstrate effectiveness as well as safety before FDA would approve a "new drug" for marketing. *Id.*; 21 U.S.C. §355 (Supp. III 1985). Congress also significantly expanded FDA's inspection authority, 21 U.S.C. §374, and required that manufacturers of pharmaceuticals register with FDA, 21 U.S.C. §360.

While expanding FDA's power over commercial drug production in 1962, the Congress at the same time carved out exclusions from FDA's authority for the express purpose of keeping the regulator out of the practice of the healing arts. Nowhere in the 1962 Amendments or in their legislative history did Congress indicate that FDA could regulate the prescribing and compounding practices of physicians and other practitioners. There is not one whit of evidence to support FDA's argument that the com-

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[17] Mr. Hutt is the co-author of a casebook on food and drug law, *Food and Drug Law -- Cases and Materials* (1979).

pounding or use of medicines in professional practices created a "new drug," nor is there any evidence that Congress intended in any way to backtrack from the protections it accorded to practitioners under the 1938 Act.

In 1962, Congress increased FDA's authority to allow it to inspect extensively "any factory, warehouse, [or] establishment" in which *prescription* drugs are made. 21 U.S.C. §374(a)(1)(B). At the same time, Congress specifically exempted from this increased inspection authority "practitioners licensed by law to prescribe or administer drugs ... who manufacture, prepare, propagate, compound, or process drugs ... solely for use in the course of their professional practice." 21 U.S.C. §374(a)(2)(B).

The 1962 Amendments also defined for the first time the terms "manufacture, preparation, propagation, compounding, or processing" and required persons who engaged in those activities to register annually. 21 U.S.C. §360(a) and (b).

> The purpose of this provision is to assist the Food and Drug Administration to identify and inspect all places where drugs are being made, and to take appropriate action (by criminal proceedings, injunction, or seizure) against those who fail to register. *It would not apply to pharmacies, or to licensed practitioners preparing drugs in the course of their professional practice*, or to persons who prepare drugs solely for use in research, teaching, or chemical analysis, and not for sale.

S. Rep. No. 1744, 87th Cong., 2d Sess. 12 (1962), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXII at 105 (emphasis added). The FDC Act accordingly separates the practitioners from commercial manufacturers, and exempts from the registration requirement licensed practitioners who "prescribe or administer drugs ... and who manufacture, prepare, propagate, compound, or process drugs ... solely for use in the course of their professional practice." 21 U.S.C. §360(g)(2).

Congress thus explicitly recognized that compounding of medicines is not to be treated like commercial manufacturing operations and that the physician or veterinarian must be free to

use drugs in a manner consistent with the needs of patients. Because of this, the district court in this case found that to require veterinarians to apply for new drug approvals is simply unrealistic and inconsistent with Congress' intent to stay out of the regulation of veterinary medicine.

There is little said in the legislative history of the 1962 Amendments about the intent of Congress not to interfere in the practice of the healing arts. Because the registration and inspection exemptions merely gave effect to the basic Act's intent, not much discussion was necessary. The 1962 Amendments, rather than subjecting practitioners to the "new drug" approval scheme, emphasized and reinforced their exclusion from it.

The Seventh Circuit, however, concluded that these exemptions would not apply to "new drugs" just as they would not apply to stolen drugs, because the court reasoned that Congress' failure to specifically mention "new drugs" in the exemptions had no more significance than its failure to mention that stolen drugs were not exempt. App. 7a. This reasoning lifts the congressional action out of its context. Congress passed the 1962 amendments for the purpose of strengthening the new drug provisions; that was the focus of the legislation. If Congress had intended to limit the applicability of §360(g)(2) and §374(a)(2)(B) to "not new" and "grandfathered" drugs,[18] it could have done so easily.[19] Congress could have stated explicitly that the exemptions in §§360(g)(2) and

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[18] "Not new" or "old" drugs are those that are "generally recognized as safe and effective" for their intended uses. 21 U.S.C. §321(w)(1). The 1938 grandfather clause exempts from the new drug definition drugs that were on the market prior to 1938 and which contain "the same representations concerning the conditions of its use" that existed in 1938. *Id.* The 1962 grandfather clause exempts from the new drug definition drugs that were on the market in 1962, were generally recognized as safe at that time, and are offered for the same uses as in 1962. 21 U.S.C.A. §360b, Historical Note (1972).

[19] The Seventh Circuit did not mention the exemption in §374(a)(2)(B). However, the court's interpretation of the Act leads to the conclusion that Congress meant to require veterinarians to obtain new drug approvals for their compounded medications but that, through the exemption provided in §374(a)(2)(B), FDA could not inspect the process by which these "new drugs" were made, or alternatively, that the exemption applies only to "not new" and "grandfathered" drugs.

374(a)(2)(B) applied only to those situations in which there were drugs that were not "new drugs." Indeed, if veterinarians were to be registered and inspected while compounding one class of drugs and not another, the need to say so would have seemed undeniable.

Alternatively, Congress could have listed specific drugs that could be compounded by veterinarians, as it listed specific antibiotic drugs in 21 U.S.C. §321(w)(3). Congress did neither and there is nothing in the Act or the legislative history to indicate that Congress meant to limit the compounding exemptions to such a small and medically insignificant class of drugs.[20] Indeed, if the Seventh Circuit and FDA are correct that the compounding exemptions were intended to be so limited, there would have been no reason for Congress to have crafted such exemptions. The exemptions, read correctly, reaffirm Congress' intent to avoid interference with the treatment decisions of licensed practitioners.

The limited view the Seventh Circuit takes of the 1962 exemptions denies them the significance they warrant, both from their plain reading and from consideration of the circumstances in which they were put into the law.

C. The Animal Drug Amendments Of 1968 Did Not Confer On FDA The Power To Control Veterinary Medicine

The Seventh Circuit did not rely upon the legislative history of the Animal Drug Amendments of 1968, and rightly so. These amendments were enacted only to incorporate in one place the various statutory provisions that affected animal drugs.[21]

At the district court level, FDA, the expert agency to which the Seventh Circuit gave deference, did not argue that the 1938 Act expressed the intent that FDA could control the practice of veterinary medicine. Rather, FDA argued that the Animal Drug

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[20] FDA's own Director of the Center for Veterinary Medicine admits that there are no finished dosage form drugs useful to the practice of veterinary medicine that are "not new" or "grandfathered" drugs. Appellees' S.A. at 45-46.

[21] Pub. L. No. 90-399, §101(b), 82 Stat. 342, 343 (1968), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIV at 683.

Amendments, by adding 21 U.S.C. §360b, changed the congressional intent and authorized FDA to exercise prior approval authority over all compounding and prescribing by veterinarians. *See* FDA Brief in Opposition to Plaintiff's Memorandum in Opposition to Claimant's Motion for Summary Judgment at 13-15. FDA argued that this control existed for veterinarians only and not for the other healing professions, such as physicians, dentists, chiropractors, chiropodists, and pharmacists. *Id.* FDA contended that this provision, which states that the "use" of a new animal drug must "conform" to the use approved in a new animal drug application, 21 U.S.C. §360b(a)(1)(B), conferred the power to require approval of each and every use of a drug by a veterinarian. FDA Brief in Opposition at 13-15.

The Seventh Circuit implicitly recognized the invalidity of FDA's contention by ignoring it. Indeed, while the Animal Drug Amendments were being considered by Congress, FDA stated on several occasions that the amendments were simply a consolidation of existing law and did not provide any new regulatory authority. For example, according to the commissioner of FDA at the time, the legislation "doesn't provide any new authority ... but simply brings it together, gives visibility to the handling of animal drugs, animal feeds."[22]

D. Congress Has In Other Acts Reaffirmed Its Intent Not To Regulate The Way Veterinarians Make And Use Medicines

Congress' intent to distinguish between commercial manufacturers and practitioners, and to refrain from the regulation of medications used by veterinarians in their licensed prac-

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[22] *Animal Drug Amendments of 1967: Hearings on H.R. 3639 Before the Subcomm. on Public Health and Welfare of the House Comm. on Interstate and Foreign Commerce*, 90th Cong., 1st Sess. 26 (1967), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIV at 351. Furthermore, Congressman Jarman, chairman of the subcommittee that conducted the hearings on the animal health industry, emphasized that the bill would not "usurp any State authority." 113 Cong. Rec. H31,293 (daily ed. Nov. 6, 1967) (statement of Rep. Jarman), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIV at 477.

tices, has continued to be reaffirmed by actions taken *after* 1968. The Drug Listing Act of 1972, Pub. L. No. 92-387, 86 Stat. 559, *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIV at 930, required those who register with FDA as drug manufacturers to submit, semi-annually, a list of all drugs manufactured by them. The purpose of the bill was to allow FDA to compile "a comprehensive inventory of drugs so that FDA can better fulfill its role of assuring that [the drugs it regulates] are pure, safe, effective, and properly labeled."[23] The final bill extensively amended 21 U.S.C. §360, *but left intact* the exemptions pertaining to licensed practitioners. The drug listing requirement applies only to manufacturers that are required to register with FDA, and therefore veterinarians are exempt from the drug listing requirement. 21 U.S.C. §360(j).

The Seventh Circuit's opinion completely ignored the implications of Congress' 1985 amendments to the Virus-Serum-Toxin Act of 1913 ("V-S-T Act"). Congress' intent to avoid regulation of the medications used in the licensed practice of veterinary medicine is emphatically confirmed by the Food Security Act of 1985, which amended the V-S-T Act. Pub. L. No. 99-198, §1768, *reprinted in* 1985 U.S. Code Cong. & Admin. News (99 Stat.) 1354, 1654-56.

While the amending act gave the Secretary of Agriculture jurisdiction over all intrastate as well as interstate shipments of animal biologics,[24] Congress expressly directed that the Secretary exempt from the licensing requirements of the V-S-T Act those who prepare such biologics "solely for administration to animals under a veterinarian-client-patient relationship in the course of the State licensed professional practice of veterinary medicine ...." 21 U.S.C. §154a(2) (Supp. IV 1987). Congress' amendment to the V-S-T Act expressly allows veterinarians to prepare biologic drugs for treatment of their animal patients *without* prior approval of the federal government.

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[23] *Drug Listing Act, 1971: Hearings on S.2167 Before the Senate Comm. on Labor and Public Welfare*, 92nd Cong., 1st Sess. 14 (1971), *reprinted in* A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments, Vol. XXIV at 825.

[24] *See* 21 U.S.C. §§151, 154, 154a (1982 and Supp. IV 1987).

The inconsistency of this action with the finding of the Seventh Circuit is vivid. Congress has deemed it within veterinarians' professional abilities to prepare their own vaccines, a type of biologic drug, and to inject those vaccines into animals, including food-producing animals such as cattle and poultry. Yet, in stark contrast, the Seventh Circuit's holding makes it illegal for a veterinarian to compound even with aspirin and water. Could the Congress have ever intended to create such an inharmonious regulatory system?

There is no way that FDA can explain why Congress would intend that veterinarians can lawfully compound biologic drugs but not other drugs. Certainly, FDA cannot contend that biologics are inherently safer than drugs that are chemicals. One appellate court has specifically pointed out that control over biologic drugs such as vaccines is even more important than control over non-biologic drugs: "The purity of these substances [biologic drugs] is of far more importance than is the purity of ordinary drugs, because the former are ordinarily introduced into the circulation directly while the latter are introduced through the digestive tract." *Blank v. United States*, 400 F.2d 302, 303 (5th Cir. 1968) (quoting S. Rep. No. 1980, 57th Cong., 1st Sess. 2 (1902); H.R. Rep. No. 2713, 57th Cong., 1st Sess. 2 (1902)).

In the proceedings below, FDA elected not to attempt to explain why Congress would, on the one hand, allow veterinarians such latitude to practice and, on the other hand, would require that FDA approve of how veterinarians will use medicines. FDA's silence is an eloquent expression of its inability to reconcile these two enactments.

III. THE SEVENTH CIRCUIT'S INTERPRETATION OF THE ACT IS IN CONFLICT WITH OTHER JUDICIAL PRECEDENT

No other court has reached the conclusion of the Seventh Circuit. Indeed, all the precedent that involves active consideration of the subject recognizes that Congress did not intend that FDA should have the authority the Seventh Circuit conferred to control the practice of the healing arts.

In *Chaney v. Heckler*, 718 F.2d 1174 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985), the court considered whether FDA was required to approve drugs used in capital punishment. It is worth repeating that *FDA* argued in *Chaney* that the state-sanctioned use of lethal injections came within a "commonly recognized exception to the Act's broad and protective coverage: the 'practice-of-medicine' exemption." 718 F.2d at 1179. FDA maintained that the regulation of licensed practitioners by the states precluded FDA's regulation of the medications used in the context of licensed practices. *Id.* (FDA's position in 1988 is exactly the opposite, but the FDC Act has not changed, and certainly the history of the FDC Act has not changed.)

The District of Columbia Circuit, in an analysis that runs to a conclusion directly counter to the Seventh Circuit's, determined that the practice of medicine exemption stemmed from Congress' express intent to avoid regulation of licensed practitioners rather than from the States' licensing authority. The court stated that "the legislative history makes clear that Congress did not want to limit a physician's ability to treat his patients." *Id.* at 1179 n.13. The court stated further that "[t]he case law under this and related statutes is consistent with our reading of the legislative history." *Id.* at 1180 n.16 (citing *United States v. Evers*, 643 F.2d 1043, 1044 (5th Cir. 1981); *United States v. Moore*, 423 U.S. 122 (1975); *United States v. Collier*, 478 F.2d 268 (5th Cir. 1973)).

The court further explained the inapplicability of the drug approval process to the use of drugs by practitioners:

> The "new drug" provisions of [the Act] require the filing of a new drug application .... 21 U.S.C. §355(b). An applicant may have to wait up to six months for action and participate in hearings. *Id.* §355(c) & (c)(2). *Hence, these "new drug" provisions simply do not fit the reality of the clinical situation.*

Id. at 1180 n.15 (emphasis added).[25] In *Chaney*, the court, and apparently FDA, recognized that "Congress would have created

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[25] In his dissent in *Chaney*, then-Judge Scalia described as "extraordinary" the "notion that a person causes an article to be misbranded by simply using it for a purpose not stated on the label." *Id.* at 1199. This is exactly the effect of the

havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses." *Id.* at 1180.[26] The Seventh Circuit concluded that Congress intended veterinarians and other practitioners to be subject to the very new drug approval process that the *Chaney* court found would create that "havoc" in the licensed practices. App. 8a.

The Seventh Circuit decision is also in conflict with *United States v. Evers*, 643 F.2d 1043 (5th Cir. 1981). In that case, FDA charged that the defendant physician, Dr. Evers, misbranded a drug within the meaning of 21 U.S.C. §352(f)(1) when he advertised and dispensed it for use by his patients for purposes other than those approved by the FDA. The court recognized that "Dr. Evers' claims for his therapy are not generally accepted by the medical profession, and ... the FDA has not approved [the drug as used by Dr. Evers]." 643 F.2d at 1045. However, the court rejected FDA's contention that medications dispensed by physicians other than according to FDA-approved labeling were misbranded. *Id.* at 1053-1054. The Fifth Circuit recognized that FDA has no jurisdiction over the preparations of licensed practitioners, and that the determination of the safety and effectiveness of those preparations was not within FDA's authority.

The Seventh Circuit relied heavily upon *United States v. Rutherford*, 442 U.S. 544, 551-553 (1979), in which this Court held that the Act contained no exemption from the new drug approval process for drugs used to treat terminally ill cancer patients. The Court thus prohibited the interstate shipment of laetrile, a drug that FDA had determined, through an administrative hearing, was a "new drug." *Id.* The Seventh Circuit said the case stood for the proposition that physicians could not obtain laetrile for their use, and that the precedent controlled this case.

Seventh Circuit's decision: a veterinarian creates a misbranded new animal drug by the way in which he uses it to treat his patients.

[26] While *Chaney* involved the unapproved use of approved drugs, the discussion of whether the new drug provisions of the Act applied to the drugs used in medical practices to treat individual patients is equally applicable to the drugs in this case. The misbranding charge is based on the status of the *preparations* of veterinarians as "new drugs," not on the status of the seized products themselves.

The issues in *Rutherford* and in this case are not the same, because in that case there was no reason to consider the medical practice exemption. The Supreme Court in *Rutherford* did not consider whether the medications compounded by licensed practitioners for use in their practices are "new drugs." Indeed, the Supreme Court never considered *any* aspect of the practice of medicine in *Rutherford*.

In *Rutherford* this Court *did* say: "Exceptions to clearly delineated statutes will be implied only where essential to prevent 'absurd results' or consequences obviously at variance with the policy of the enactment as a whole." 442 U.S. at 552 (citations omitted). This Court then considered the legislative history and administrative interpretation of the FDC Act to find there was no exemption for the terminally ill. 442 U.S. at 552-59. Because it is so firmly developed in the legislative history and administrative interpretation of the FDC Act, the Seventh Circuit should have recognized the exemption for practitioners.

Pharmaceutical Manufacturers Association v. FDA, 484 F. Supp. 1179 (D. Del.), *aff'd*, 634 F.2d 106 (3d Cir. 1980), casts light on the proper bounds of FDA's authority. In *PMA*, the agency required the dispensing of information to patients about the drugs they were to take. *Id.* at 1181. The *PMA* court looked at the *quality* of the activity to conclude that the issue in the case was not about a "right to exercise judgment in prescribing treatment" but rather a "right to control patient access to information." *Id.* at 1188.

The quality of the activity that FDA would regulate in this case is something more than the withholding of information to which a patient is entitled. Indeed, the activity here is at the very core of the practice. So central is it that, if FDA gets the power it seeks, the ability to carry out that essential professional responsibility will be destroyed, and we all will suffer. No case can be found to support the proposition that it is within the power of FDA to control the practice of veterinary medicine from Washington.

Another court has looked at the issue tangentially in interpreting the Controlled Substances Act (CSA), 21 U.S.C. §§801-904. The First Circuit in *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987), recognized that Congress did not intend to control the

prescriptions of physicians through the CSA. That court considered whether a substance controlled by the Drug Enforcement Agency (DEA) could be deemed to have a "currently accepted medical use" if it had not been approved by FDA. The First Circuit rejected DEA's claim that "current medical use" meant FDA approval and stated that "it is plainly possible that a substance may fail to obtain ... approval even if it has an accepted medical use." *Id.* at 887. The First Circuit recognized that medical practice and research are not synonymous with FDA approval. *Id.*

IV. FDA'S INTERPRETATION OF THE ACT IS INCONSISTENT WITH PAST AND CURRENT POLICIES

The Seventh Circuit gave deference to the agency's *conclusion* that it should have authority over medicines compounded and used by veterinarians, finding the agency's authority in the history of the basic Act. In fact, the Seventh Circuit gave FDA authority that it did not argue that it should have (that is, over all practitioners who use drugs) and FDA did not argue that its authority came from the 1938 basic Act.

The agency to which the Seventh Circuit gave deference has accumulated a formidable record of inconsistency in dealing with the issue at hand. Past agency practice has actually tolerated compounding and in some cases expressly authorized it. The Seventh Circuit's decision also applies to human drug therapy and there it unequivocally contradicts FDA policy.

On October 10, 1944, FDA issued a regulation that exempted bulk drugs from the adequate directions for use requirement. 9 Fed. Reg. 12,255 (1944). That regulation authorized the shipment of bulk drugs to veterinarians and other practitioners and defined the term "manufacture" as excluding "the use of a drug as an ingredient in compounding any prescription issued by a physician, dentist or veterinarian in his professional practice." *See* 21 C.F.R. §2.106(k)(1), 9 Fed. Reg. at 12,256. Therefore, it is clear that FDA, although regulating bulk drugs, did not regulate the compounding of such drugs by practitioners.

More inconsistency is seen in FDA's compliance policy guides,[27] such as Compliance Policy Guide 7125.18, which is dated September 22, 1977, and is entitled "Human Drugs for Animal Use." Appellees' S.A. at 132. This guide was amended in 1980 and therefore was in effect until at least that time. (Petitioner does not know when or if this guide was revoked and FDA has not said.) The 1977 compliance policy guide stated that:

> [I]t is generally accepted that licensed veterinarians may compound their own prescriptions and may thus lawfully obtain prescription chemicals from pharmacy supply houses under local professional practice laws.

This policy attempted to balance the requirements of the FDC Act and "state laws and accepted practices governing the conduct of licensed practitioners." Appellees' S.A. at 133. In accordance with this policy FDA "has not in the past denied veterinarians the right to treat animals in accordance with the dictates of their conscience and within the bounds of accepted veterinary medical practice." *Id.* Although FDA did not *sanction* the use in a food-producing animal of a drug for which there is no specific FDA approval, FDA said that such use is the responsibility of the veterinarian. *Id.* FDA did *not* say that such use creates a new animal drug and is illegal. There is simply no way to square this compliance policy guide with FDA's current policy.[28]

In a 1976 FDA compliance policy guide, the agency stated that:

> [V]eterinarians may use in the compounding of prescriptions for their private practice whatever bulk drugs or other pharmaceuticals they may lawfully purchase. This falls under the general practice of veterinary medicine

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[27] FDA regularly issues documents that are known as compliance policy guides. Compliance policy guides state FDA's official opinions and are binding on FDA unless amended or revoked. 21 C.F.R. §10.85(e) (1988).

[28] FDA's most recent approach is stated succinctly in Compliance Policy Guide 7125.06, "Extra-Label Use of New Animal Drugs in Food-Producing Animals" (November 1, 1986): "The use or intended use of new animal drugs in treating food-producing animals in any manner other than in accord with the approved labeling causes the drugs to be adulterated ...." Appellees' S.A. at 119.

> which is amenable to local or State laws with which FDA has no desire to interfere.

FDA Compliance Policy Guide 7125.10, "Veterinarian Use of New Animal Drug Substances" (July 13, 1976), Supplemental Appendix for the Appellant in the Seventh Circuit at 30. FDA makes no mention, in this document, of any need for prior approval of the uses the veterinarian will make of these bulk materials, nor does FDA contend that a veterinarian's compounding would produce a violative, unapproved new animal drug.[29]

It is uncertain whether this compliance policy guide was intended to have any substantive meaning or whether its promulgation was simply a sham. The apparent general policy that a veterinarian can lawfully compound drugs is completely undercut if, as FDA seems to say, the veterinarian cannot legally receive the bulk drugs he needs to compound.[30]

The inconsistency of FDA's policy is demonstrated by the 1985 congressional testimony of a former director of FDA's Center for Veterinary Medicine:

> [P]rior to that time [1983 and 1984] the policy of the Food and Drug Administration for veterinarians was, and I quote:
>
> Veterinarians may use any drug they may legally obtain in their practices in accordance with their professional judgment and as long as they did not cause illegal residues.

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[29] This compliance policy guide says that it would not apply, however, to "bulk new drug or new animal drug substances." *Id.* The term "new animal drug substance" is an invention of the agency and cannot be found in the Act. FDA attempted, through this artifice, to regulate as "new drugs" those substances that would be used to produce new animal drugs.

[30] A third compliance policy guide adds to FDA's confusion. FDA states that: When a *bulk chemical* has a bonafide use in human or animal medicine not requiring approval, it may be shipped domestically or imported for that use provided it is not offered or intended for an unapproved use. Compliance Policy Guide 7125.20, "Availability of Bulk Chemicals for Animal Drug Use" (October 1, 1980), Appellees' S.A. at 137 (emphasis added). Because FDA does not approve bulk chemicals, the statement makes no sense.

> When we changed the policy, we tightened down on that considerably. We said no longer could veterinarians have the impunity to use any drug they could legally obtain.[31]

FDA's own statements, still "in effect," show why deference should not be given to an agency that plainly has no consistent policy. The Seventh Circuit's opinion makes clear that its rationale applies with equal force to *any* practitioner who uses drugs, including physicians; that is, the court says FDA has primary power over any drug therapy. App. 5a. But FDA, the expert agency, has, in language at dramatic variance to the Seventh Circuit decision, expressly rejected the notion that it has such authority. Speaking in the context of the unapproved use by physicians of marketed approved new drugs -- which could of course include compounding -- FDA says:

> Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.
>
> This interpretation of the Act is consistent with congressional intent as indicated in the legislative history of the 1938 Act and the drug amendments of 1962. Throughout the debate leading to enactment, there were repeated statements that Congress did not intend the [FDA] to interfere with medical practice and references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and patient.

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[31] *The Regulation of Animal Drugs by the Food and Drug Administration: Hearings Before the Subcomm. on Intergovernmental Relations and Human Resources of the House Comm. on Government Operations*, 99th Cong., 1st Sess. 263 (1985) (statement of Lester M. Crawford, Director, Center for Veterinary Medicine, Food and Drug Administration). This testimony proves the absurdity of FDA's claim that in 1962 Congress ratified FDA's present interpretation of 21 C.F.R. §201.122. Appellant's Brief in the Seventh Circuit at 30 n.35.

> Congress recognized a patient's right to seek civil damages ... if there should be ... malpractice, and declined to provide any legislative restrictions upon the medical profession.

37 Fed. Reg. 16,503 (1972). FDA repeated this interpretation of the FDC Act in 1987. 52 Fed.Reg. 8798, 8803 (1987). This FDA interpretation of the law and the legislative history of the basic Act and the 1962 amendments contradicts the Seventh Circuit, though the court considered that it was deferring to the agency's interpretation of the law.

It is clear that FDA has been anything but consistent.[32] Such inconsistency is not entitled to deference. *Adamo Wrecking Co. v. United States*, 434 U.S. 275, 287 n.5 (1978); *United Transportation Union v. Lewis*, 711 F.2d 233, 242 (D.C. Cir. 1983) ("[a] statutory construction to which an agency has not consistently adhered is owed no deference"). It may be difficult to track FDA's interpretation of the law concerning veterinarians, but it is certain that the agency's interpretation about its authority over physicians is inconsistent with the ruling made by the Seventh Circuit.

In addition, an agency's interpretation of the statutes it administers is entitled to deference only if that interpretation is rational. *Young v. Community Nutrition Institute*, ___ U.S. ___, 106 S. Ct. 2360, 2364-65 (1986); *Chemical Manufacturers Assn. v. Natural Resources Defense Council*, 470 U.S. 116, 125 (1985). The director of FDA's Center for Veterinary Medicine has described the irrationality of FDA's policy. *He stated that there are disease entities for which there are not FDA-approved drugs and that to treat these diseases a veterinarian must practice medicine in violation of the law as FDA interprets it.* Appellees' S.A. at 65-68. Dr. Guest acknowledged that FDA's interpretation of the Act did not coincide with the ethical practice of veterinary medicine. Appellees' S.A. at 69-71. A governmental scheme of regulation that requires a profession to engage in criminal acts to preserve the health of the public and patients cannot be considered rational. Such an interpretation of the Act is entitled to no deference.

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[32] In 1973, FDA agreed that a veterinarian *could* in the course of his practice ship unapproved drugs in interstate commerce and not be the subject of "new drug" charges. *United States v. Cockerill*, 366 F. Supp. 856, 857-858 (S.D. Ill. 1973).

V. THE SEVENTH CIRCUIT'S OPINION MISREADS SEVERAL FUNDAMENTAL FACTS AND CIRCUMSTANCES

A. FDA's Extra-Label Use Policy Does Not Immunize Veterinarians From The Risk Of FDA Enforcement Actions

The Seventh Circuit concluded that FDA could have prosecuted "thousands of individual veterinarians" for using "new drugs" that they compounded. That is no doubt why the court found some latitude in FDA's extra-label use policy -- set forth in Compliance Policy Guide 7125.06 (Nov. 1, 1986) -- saying that it is a "non-enforcement policy related to the one sustained in *Heckler v. Chaney*." App. 8a. The *Chaney* decision recognized that FDA did not have to exercise its enforcement authority to prevent unapproved drugs from being used for unapproved purposes, that is for executions. However, the latitude of the extra-label use policy is an illusion: the policy is FDA's statement that it will prosecute any veterinarian it chooses when drugs are used except as FDA prescribes. Some veterinarians are identified as less likely to be prosecuted, but as the commissioner has said, any veterinarian who exercises judgment beyond the FDA-approved labeling "does so at his own peril." Appellees' S.A. at 74. This "non-enforcement policy" is nothing more than a malpractice Pandora's box. If the use of a drug for a purpose not approved by FDA is illegal, veterinarians will find themselves at an increased risk that they will be liable for both punitive and compensatory damages for any injuries that occur, even if their treatments are ethically correct. *See, e.g., Stanton v. Astra Pharmaceutical Products*, 718 F.2d 553, 563-564 (3d Cir. 1983) (violation of government safety regulation constitutes negligence *per se*).

The record in this case establishes that the ethical practice of veterinary medicine and FDA's scheme of regulation as approved by the Seventh Circuit are not coextensive. The extra-label use policy does nothing to relieve this, except to invite veterinarians with sufficient daring to risk fines and imprisonment to practice medicine properly.

B. Veterinarians Are Properly Trained To Compound Drugs

The foremost concerns of veterinarians are the health of consumers of animals used as food sources, and of the animals themselves.[33] Compounding of medicines is absolutely necessary to the correct practice of veterinary medicine.[34] Veterinary medical schools and the veterinarians' own continuing education provide extensive training in chemistry and pharmacology to enable them to compound and prescribe effectively.[35] Veterinarians, to do their task properly, must be able to use drugs in a manner consistent with the health of the animals and, in the case of food-producing animals, the consuming public's health.[36] None of the foregoing was contested by FDA.

C. FDA's Action Is Inconsistent With The Proper Practice Of Veterinary Medicine

FDA's director of veterinary medicine *admits* that FDA's interpretation of the Act is inconsistent with the ethical practice of veterinary medicine. Appellees' S.A. at 69-71. Moreover, it is also inconsistent with FDA's own application of the Act with respect to finished form veterinary drugs. In contrast to FDA's desire to regulate veterinarians, FDA has admitted that approximately 90 percent of finished form veterinary drugs on the market, all considered "new," are not FDA-approved.[37]

Bulk drugs provide veterinarians with the necessary flexibility to assure the health of the animals they treat.[38] It makes

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[33] Clack Statement at ¶3, Appellees' S.A. at 22; Crouch Statement at ¶4, Appellees' S.A. at 27-28; Skiles Statement at ¶8, Appellees' S.A. at 32; VanDamme Statement at ¶8, Appellees's S.A. at 38-39.

[34] *See, e.g.*, Clack Statement at ¶4, Appellees' S.A. at 22-23; Crouch Statement at ¶7, Appellees' S.A. at 29.

[35] Crouch Statement at ¶4, Appellees' S.A. at 27-28.

[36] *See, e.g.*, Clack Statement at ¶¶3-5, Appellees' S.A. at 22-23.

[37] *The Regulation of Animal Drugs by the Food and Drug Administration: Hearings Before the Subcomm. on Intergovernmental Relations and Human Resources of the House Comm. on Government Operations*, 99th Cong., 1st Sess. 29 (1985).

[38] Clack Statement at ¶9, Appellees' S.A. at 25; Skiles Statement at ¶7, Appellees' S.A. at 32.

no sense to try to use finished form drugs to compound medications because the finished form drug must be altered to fit the needs of the situation and patient, the finished form drug contains unnecessary ingredients, and quality pure bulk drugs are available.[39] In some instances, bulk drugs are the *only* available treatment, and failure to use them would result in the death of many animals.[40] Again, none of the foregoing was contested by FDA.

D. Veterinarians Are Subject To Legal Scrutiny

The Seventh Circuit dealt skeptically with the controls that are available to govern the conduct of veterinarians, expressing the belief that civil liability and professional discipline were not adequate. App. 6a. Whether veterinarians' pockets are "deeper" than those of pharmaceutical companies and whether veterinarians and physicians are sufficiently accountable to their states under the criminal codes and the licensing authorities should not determine how to read the FDC Act.

But neither petitioner nor the individual veterinarians claim any blanket immunity under the law. This case does not involve the question of whether veterinarians can become drug manufacturers without prior FDA approval. Veterinarians who act outside the scope of their practices have the standing of laymen, *cf. United States v. Moore*, 423 U.S. 122 (1975), and as such have no right to receive or compound any bulk materials that a layman could not obtain. Further, should a veterinarian misuse any medicines and harm the animals or cause residues in the food, then all recognize that a veterinarian could be prosecuted under the FDC Act for adulterating food.[41] Also, the veterinarian would be subject to disciplinary action by the state licensing authorities and the profession. *See, e.g.*, Ill. Ann. Stat. ch. 111, ¶7025 (1986).

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[39] *Id.*

[40] Westlake Statement at ¶6, Appellees' S.A. at 40-41.

[41] 21 U.S.C. §342; Compliance Policy Guide 7125.06, "Extra-Label Use of New Animal Drugs in Food-Producing Animals" (Nov. 1, 1986).

VI. CONCLUSION

The activity under consideration in this case is the compounding and prescribing of medicines by veterinarians. Drug therapy is essential to treatment regimens, in animals as well as man. Congress wisely never intended to give FDA the destructive control it seeks; veterinarians must prescribe for patients, not federal regulators. The district court correctly interpreted the law to deny FDA the ability to assert prior approval over veterinarians' use of each and every medicine for each patient and condition. App. 22a.

For reasons that do not appear in the record, the Seventh Circuit found that veterinarians and others who administer medicines are not able to calculate patient treatment regimens as well as FDA; the court cited the example of diethylstilbestrol. App. 6a. Nothing in our system, including FDA, can guarantee perfect safety. On the other hand, the record in this case abundantly establishes that a quick and easy way to assure catastrophe is to insert government bureaucracy into every individual patient treatment decision. The legislative history of the FDC Act recognizes the need for latitude when professionals treat their patients, and establishes the exemption which the Seventh Circuit denied.

For all of these reasons, this Court should exercise its discretion to review the Seventh Circuit's decision in this case because it decides an important question of federal law which has not been, but because of its importance should be, settled by this Court.

Respectfully submitted,

James R. Phelps
Counsel of Record
Robert A. Dormer
Hyman, Phelps & McNamara, P.C.
1120 G Street, N.W.
Washington, D.C. 20005
(202)737-5600

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In the
UNITED STATES COURT OF APPEALS
For the Seventh Circuit

No. 88-1233

United States of America,

Plaintiff-Appellant,

v.

9/1 KG. CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE,

Defendants-Appellees.

Appeal from the United States District Court
for the Central District of Illinois, Springfield Division.
No. 86-3201-Richard Mills, *Judge*.

ARGUED JUNE 9, 1988–DECIDED JULY 27, 1988

Before EASTERBROOK and MANION, *Circuit Judges*, and ESCHBACH, *Senior Circuit Judge*.

EASTERBROOK, *Circuit Judge*. No one may sell a new animal drug, or feed containing a new animal drug, without the approval of the Food and Drug Administration. 21 U.S.C. §360b. Obtaining approval takes a long time and costs a lot of money, for the FDA requires thorough experimentation to determine both the drug's effects on animals and whether its residues persist in the animals and enter the food chain. A drug that leaves potentially-dangerous residues will not be approved. Scientists' ability to determine the long-range effects of many chemical substances is limited; that lack of knowledge, coupled with the FDA's cautious approach, means that few new animal drugs have been approved. We must take it as given that for significant diseases there are no

effective FDA-approved drugs. Acute mastitis, which may decimate a herd of dairy cattle in short order, cannot be treated with approved new animal drugs; neither can shipping fever and salmonella in feedlot cattle. The FDA has not approved any general anesthetic for field use in surgery on food animals. For the principal diseases of non-food animals, such as mink and fox, there are few, if any, approved remedies.

Many veterinarians find this state of affairs deplorable. Because they cannot buy in finished form the drugs they think they should be able to use, they have elected to make their own. They purchase the active ingredients, mix them in the proportions they think best, and administer their concoctions as professional judgment dictates. The veterinarians do not sell the drugs, so the FDA's usual methods of control do not come into play. The FDA looked the other way for decades. Cf. *Heckler v. Chaney*, 470 U.S. 821 (1985). Recently, however, the FDA became concerned about the end-run around its approval process-perhaps because the practice has become widespread-and decided to put a stop to it. The FDA might have prosecuted thousands of individual veterinarians for administering unsafe drugs (any new animal drug is deemed unsafe unless approved by the FDA, 21 U.S.C. §360b(a)), but the agency thought it easier to cut off the veterinarians' supply of active ingredients. This case is the result.

The FDA decided to intercept the drugs in the hands of the middleman: in this case Schuyler Laboratories, Inc., which purchased unblended ingredients from their manufacturer and resold them, still in bulk, to veterinarians. Such a middleman does not manufacture drugs and therefore ordinarily does not need to seek the FDA's approval via new animal drug applications. (Things may be different when the drug is an antibiotic listed in 21 U.S.C. §321(w)(3); we shall not have to decide.) In July 1986 the FDA swooped down on Schuyler and seized every container of drugs on the premises. It carted off 52 lots and filed a complaint seeking their forfeiture as "misbranded" drugs. See 21 U.S.C. §334(a)(1). (How the caption of this case came to be as it is baffles us.) The bulk drugs were "misbranded", according to the FDA, as a result of this requirement in 21 U.S.C. §352:

> A drug or device shall be deemed to be misbranded-
>
> . . .
>
> (f)Unless its labeling bears (1) adequate directions for use; . . . *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary [of Health and Human Services] shall promulgate regulations exempting such drug or device from such requirement.

The labels of the containers on Schuyler's premises gave the name of the drug and its manufacturer, but no directions for use. It would be difficult to create labels with such directions, because bulk drugs are to be mixed or otherwise compounded rather than used in their current form. The drugs are therefore "misbranded" unless Schuyler can take advantage of the proviso.

> The regulation implementing the proviso states:
>
> A drug in a bulk package, except tablets, capsules, or other dosage unit forms, intended for processing, repacking, or use in the manufacture of another drug shall be exempt from §502(f)(1) [21 U.S.C. §352(f)(1)] of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking"; . . . . But the exemption shall not apply to a substance intended for use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:
>
> (a) An approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder by persons named in the application . . . .

21 C.F.R. §201.122. Schuyler's bulk drugs do not qualify under this regulation as written, because although they are "intended for use in manufacture" (etc.) Schuyler has not offered to show that an approved new animal drug application covers the substance that will ensue. Schuyler argues that the qualification in the regulation starting with "But the exemption shall not apply . . ." is unlawful because not "necessary for the protection of the public

health" within the meaning of §352(f). In other words, Schuyler wants the benefits of the first sentence of §201.122 without the burden of satisfying the remainder of the regulation. Everything after the first sentence, Schuyler believes, must be discarded; the bulk drugs would come within the remaining language.

The district court agreed with Schuyler and ordered the FDA to return the drugs. 674 F. Supp. 1344 (C.D. Ill. 1987). Accord, *United States v. Algon Chemical Inc.*, No. 87-1820 (D.N.J. Apr. 12, 1988). As it saw things, the limits on the permission to sell unlabeled bulk drugs are neither necessary nor prudent for three reasons: Congress wanted to leave medical professionals free to practice as their judgment required; veterinarians are not regulated in compounding drugs, implying liberty to obtain drugs to compound; and the middleman cannot know whether its customer has the necessary approval. We stayed the district court's order pending appeal.

The statute treats drugs without directions for use as presumptively misbranded. Schuyler bears the burden of establishing its entitlement to treatment under the exception. *United States v. An Article of Device "Toftness Radiation Detector"*, 731 F.2d 1253, 1260-62 (7th Cir. 1984). Whether there is a safe harbor for Schuyler to seek depends in the first instance on the FDA's judgment about the conditions necessary to protect the public health. The phrase "necessary for the protection of the public health" in §352(f), like the phrase "public interest, convenience, and necessity" in other regulatory statutes, delegates authority to an agency. See *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 321 (1981); *Colorado v. United States*, 271 U.S. 153, 168-69 (1926); *Black v. ICC*, 737 F.2d 643, 650 (7th Cir. 1984). It requires the agency to make a judgment about where the public interest lies. Courts defer to the FDA when it construes its governing statutes. E.g., *Young v. Community Nutrition Institute*, 476 U.S. 974 (1986); cf. *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.* 467 U.S. 837 (1984); *Continental Air Lines, Inc. v. Department of Transportation*, 843 F.2d 1444, 1448-54 (D.C. Cir. 1988). The FDA's task was not, however, to "construe" a statute. It was to make a judgment about a medi-

cal subject. Someone must draw on knowledge about risks and needs and decide how much risk is too much; that someone is the Executive Branch of the government. "[T]he first question in determining the deference appropriate to the agency[]. . . is whether Congress has transferred discretion to the agency. If the legislation either calls for the agency's decision or contains no disposition of the subject, then the agency has been deputized to make a rule, and its decision should be respected." *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 411 (7th Cir. 1987). So Schuyler is fighting a doubly-uphill battle: it bears the burden of establishing an exception to the labeling requirement, which it can get only by showing that the FDA's views about the needs of public health are arbitrary and capricious.

The district court thought that they are because "it was not the purpose of the Act to involve the agency in the practice of the healing arts." 674 F. Supp. at 1348. If not that, however, what *does* the statute do? Congress gave the FDA comprehensive powers to license the manufacture of drugs and limit their sales. To regulate drugs is to be "involved" in the "practice of the healing arts." True, the Senate report that accompanied the original statute in 1935 said that the bill was "not intended as a medical practices act and [would] not interfere with the practice of the healing art[s]", S. Rep. No. 361, 74th Cong. 1st Sess. 3 (1935), but the statute has undergone much amendment since then, including a complete over-haul in 1962. Phrases such as the one in the 1935 Senate report-not repeated in 1962-never meant more than that medical licensure and discipline would continue to be the states' business; states, not the FDA, would decide whether (for example) physicians had selected wisely from among methods of treatment. The full quotation, redacted by Schuyler and the district court, makes the point: the statute is "not intended as a medical practices act and [would] not interfere with the practice of the healing art *by chiropractors and others*". So states set medical qualifications, and practitioners who do not use drugs (i.e., chiropractors) may go on as before. Nothing in the history or structure of the Act permits drugs deemed ineffective or dangerous by the FDA to be available for use. *United States v. Rutherford*, 442 U.S. 544 (1979).

We do not question the good will of physicians, veterinarians, and other medical professionals. Still, no individual veterinarian will possess complete knowledge of the efficacy of a novel drug compound-let alone of its persistence in the food chain. The testing required to obtain a new animal drug approval is costly and extended precisely because information is so difficult to come by. Testing must isolate the effects of the drug in question from all other environmental influences, then follow the animals for years (even generations of animals) to identify the consequences. This requires data from large populations of animals and the application of powerful statistical techniques. No solitary medical professional can carry out this program of knowledge acquisition for even one drug, let alone for the bevy of drugs a veterinarian may choose to compound. All the good judgment in the world is useless when we lack essential knowledge.

Schuyler (and the veterinary groups supporting it as *amici curiae*) responds that if veterinarians err in compounding and administering novel drugs, they will be subject to professional discipline, and the sellers of the afflicted animals to tort liability. All very well, *if* the sellers and veterinarians had the wealth to pay what could turn out to be staggering tort judgments, and *if* it should prove possible to trace cancers developing 20 years hence to residues in particular animals treated by particular veterinarians. But the sellers and veterinarians do not have the wealth needed to compensate all potential victims fully, and it would be difficult-more likely impossible-to attribute loss to a particular source many years after the fact. One need only think of the complexities of DES litigation to see a shadow of what would happen if courts had to trace drugs back through the food chain to find their sources. Even though DES was administered directly to patients, it is often impossible to identify the seller of the particular drug, and identified sellers may be out of business.

Some of the bulk drugs seized from Schuyler pose risks. Schuyler was holding for sale dimatridazole and nitrofurans, both of which have been found to cause cancer in animals and inferentially to pose a risk to humans. The FDA has withdrawn existing approvals to sell finished drugs containing dimatridazole, 52 Fed.

Reg. 25312 (1987), and has proposed to withdraw approvals for finished nitrofuran products, 49 Fed. Reg. 34965 (1984). Schuyler nonetheless believes that veterinarians (and other medical professionals) should be free to compound drugs containing these ingredients, in their sole judgment. Reasonable persons could think it appropriate to rely on tort law and professional discipline, despite the difficulties we have outlined, to assure the safety of drugs used in food animals (and for other purposes), but Congress and the FDA have reached a different conclusion.

The district court believed, however, that Congress made an earnest of its desire to steer clear of regulating medical judgment by excluding veterinarians from several features of the regulatory system. For example, although the manufacture of drugs is tightly controlled, Congress exempted from these controls practitioners who "prescribe or administer drugs. . .and who manufacture, prepare propagate, compound, or process drugs. . . solely for use in the course of their professional practice." 21 U.S.C. §360(g)(2). The district court reasoned: "It makes no sense for Congress to grant this exemption. . .if it then takes away the very drugs that would be compounded." 674 F. Supp. at 1349.

This conclusion depends on a suppressed assumption: that §360(g)(2) covers *all* drugs, rather than only drugs made from components that lawfully may be obtained and compounded. There isn't any support for the assumption. The straightforward reading of this language is the one the FDA gives it: "[V]eterinarians may use in the compounding of prescriptions for their private practice whatever bulk drugs or other pharmaceuticals they may lawfully purchase." FDA Compliance Policy Guide §7125.10 (July 13, 1976). It does not guarantee that any particular drug will be available lawfully. *Rutherford* shows as much in holding that physicians may not obtain laetrile for administration to dying patients, even on the assumption that the drug is harmless and the prescription (or compounding) private. The FDA treats §360(g)(2) as allowing veterinarians to "prepare, propagate, compound, or process drugs *from ingredients they lawfully acquire*", and the added words are no more than those implied in every statute. Schuyler does not say that §360(g)(2) allows veterinarians to steal

drugs in order to compound them, or to import drugs that are otherwise banned; no more does it allow them to obtain drugs that are otherwise mislabeled. To the extent there is any doubt, we accept the FDA's reading of its own statute. *Young v. Community Nutrition Institute*. Medical professionals may use their privilege under §360(g)(2) to mix drugs available outside the new drug application system-"grandfathered" drugs available in 1935 and recognized then as safe and effective. They also may further compound drugs that have been approved by the FDA, to at least a limited extent. This "extra-label use" is governed by a non-enforcement policy related to the one sustained in *Heckler v. Chaney*. If the need is great and the risk is small, the FDA will not contend that re-mixing approved drugs, or using them in a way other than per directions on the label, causes their "adulteration" under the act. FDA Compliance Policy Guide §7125.06 (Nov. 1, 1986).

The district court's final objection to §201.122 was that "it shifts to the claimant an unreasonable burden to show that the exemption applies. . . . Because of the nature of bulk drugs. . ., it is impossible to tell, at this stage whether the finished product will be a new drug since there is no finished product yet. Thus, the FDA would force the claimant to produce proof which is non-existent in order to invoke exemption. This result is unreasonable." 674 F. Supp. at 1349. It is not, however, "impossible" to tell what will become of bulk drugs. The seller need only ask the buyer what use lies in store. If the answer discloses impending compounding that would produce a "new animal drug", the seller must ask the buyer to display a filed or granted new drug application. That inquiry would not detain Schuyler, because it is stipulated that (a) all of its sales are to veterinarians, and (b) not a single veterinarian in the United States holds an approved new animal drug application for any drug, and none has such an application on file. More: The Federal Register contains a list of all filed and approved new animal drug applications, so Schuyler could check through that source as well. The task of inquiry set by the regulation, far from being "impossible", turns out to be easy. The easy answer reveals that Schuyler can never *satisfy* this aspect of the regulation when

individual veterinarians are the buyers, but this is different from showing that it is impossible to acquire essential information.

The effect of §352(f) and §201.122 is that ingredients that can be used to produce "new" drugs may be sold only to firms that hold approved (or have filed) new animal drug applications. The FDA carefully scrutinizes the activities of these manufacturers. This is a sensible result in light of the structure of the statute.

The statute itself is not universally praised. As Schuyler points out, the FDA has not approved drugs adequate to deal with significant animal diseases. Careful scholars have concluded that the FDA is overly cautious, deprecating benefits and overestimating risks in a way that keeps beneficial drugs off the market, while unduly deferring the introduction of other drugs and raising the cost (and, ironically, the riskiness) of drugs finally made available. E.g., David Leo Weimer, *Safe-And Available-Drugs*, in **Instead of Regulation: Alternatives to Federal Regulatory Agencies** 239 (Robert W. Poole, Jr., ed. 1982); Sam Peltzman, *The Health Effects of Mandatory Prescriptions*, 30 J.L. & Econ. 207 (1987). The certification process hampers small firms and may produce a concentrated industry with higher prices still. Cf. Peter Temin, **The Role of Regulation and Technology in the Creation of the Modern Pharmaceutical Firm** (1978). It may be no accident that the trade associations of the large drug houses have appeared in this case as *amici curiae* in support of the FDA. Perhaps the individual judgment of medical professionals (including the pharmaceutical houses that do not recklessly expose their treasuries to depletion in tort litigation) does better than bureaucratic judgment despite the difficulties we have mentioned. Subjects such as these are for Congress and the FDA to consider. Judges' role is to decipher and enforce the existing scheme, whatever they think of its wisdom.

The statute essentially forbids the sale, in any form, of drugs formulated or put to new uses after 1935, without the approval of the FDA. Schuyler, which bears the burden of proof, has not offered to show that the FDA has approved the formulations and uses its customers would make of its bulk drugs. The statutory "hook" for implementing the prohibition is the labeling rule. The 52 lots of bulk drugs seized from Schuyler are mislabeled under

§352(f), and Schuyler does not come within the regulatory exemption. The drugs are forfeit.

REVERSED

UNITED STATES of America, Plaintiff,

v.

9/1 KG CONTAINERS, More or Less of an ARTICLE OF DRUG FOR VETERINARY USE, et al., Defendants.

No. 86-3201.

United States District Court,
C.D. Illinois,
Springfield Division.

Dec. 8, 1987.

Government sought condemnation of bulk animal drugs for misbranding and adulteration. Seller of bulk drugs to veterinarian moved for summary judgment. The District Court, Mills, J., held that: (1) bulk drug exemption from labeling requirement was out of harmony with statutory intent to extent that it did not apply to seller of bulk drugs unless seller could show that finished product was not new drug or that new animal drug application was secured, and (2) bulk animal drugs were not new animal drugs and were not dangerous or adulterated.

Motion granted.

1. Drugs and Narcotics

Government claiming that bulk animal drugs were misbranded had burden to show by preponderance of evidence that seized drugs were intended for use in animals, that they did not bear adequate directions for use, and that drugs were held for sale after shipment in interstate commerce. Federal Food, Drug, and Cosmetic Act, § 502(f)(1), as amended, 21 U.S.C.A. § 352(f)(1).

2. Drugs and Narcotics

Regulation exempting bulk drugs from labeling requirement, unless use of bulk drug would result in finished product which was

new drug, was not in harmony with letter and intent of labeling requirement statute to extent that seller of bulk drugs to veterinarians would not enjoy exemption unless finished product was not new drug or new drug application was approved; extent to which Food and Drug Administration intended to involve itself in healing arts was inconsistent and not in harmony with statutory intent. Federal Food, Drug, and Cosmetic Act, §§ 201(w)(3), 501(a)(5), 502(f)(1), 512(a)(1), as amended, 21 U.S.C.A. §§ 321(w)(3), 351(a)(5), 352(f)(1), 360b(a)(1).

3. Drugs and Narcotics

Regulation exempting bulk drugs from labeling requirement, unless use of bulk drug would result in finished product which was new drug, unreasonably shifted burden to seller of bulk drugs to veterinarians to show that finished product in which bulk drug was used was not new drug or that new animal drug application had been approved; bulk drugs were compounded with other drugs and substances to make finished product; it was impossible to tell whether finished product would be new drug; and seller could not secure application without idea of what drug would be produced. Federal Food, Drug, and Cosmetic Act, § 502(f)(1), as amended, 21 U.S.C.A. § 352(f)(1).

4. Drugs and Narcotics

Remedy for regulation, which exempted bulk drugs from labeling requirement and which was out of harmony with letter and intent of labeling requirement, was to read regulation as consistent with statute to extent possible; thus, regulation exempted bulk drugs from general requirement, but did not require seller of bulk drugs to veterinarians to show that finished product in which bulk drug was used was not new drug or that new animal drug application was approved. Federal Food, Drug, and Cosmetic Act, § 502(f)(1), as amended, 21 U.S.C.A. § 352(f)(1).

5. Drugs and Narcotics

Bulk animal drugs consisting of ampicillin trihydrate, amoxicillin trihydrate, tetracycline HCL, streptomycin sulfate, and penicillin V potassium were not in finished dosage form, were not

intended for use in animals in present form, were not "new animal drugs," and were not unsafe or adulterated. Federal Food, Drug, and Cosmetic Act §§ 201(w)(3), 501(a)(5), 502(f)(1), 512(a)(1), as amended, 21 U.S.C.A. §§ 321(w)(3), 351(a)(5), 352(f)(1), 360b(a)(1).

See publication Words and Phrases for other judicial constructions and definitions.

James A. Lewis, Asst. U.S. Atty., Springfield, Ill., for U.S.

John Ess, Heyl, Royster, Voelker & Allen, Springfield, Ill., for amicus curiae American Veterinary Medical Assoc.

Philip C. Olsson, David P. Weeda, Arthur Y. Tsien, Olsson, Frank and Weeda, P.C., Washington, D.C., for amicus curiae American Feed Industry Assn.

James R. Phelps, Robert A. Dormer, Hyman, Phelps & McNamara, P.C., Washington, D.C., William F. Trapp, Springfield, Ill., for defendants.

LeFevre, Zeman, Oldfield & Schwarm, Vandalia, Ill., for American Food Animal Veterinary Medical Assn.

OPINION

MILLS, District Judge:

In this cause, the Government seeks the condemnation of bulk animal drugs pursuant to 21 U.S.C. § 334.[1] As this is a case of first impression, we proceed with very little in the way of case law to guide us.

The Government alleges that the drugs do not have adequate directions for use and are, therefore, misbranded. Additionally, the Government claims that five of the lots are subject to condemnation because they have not been approved by the Food & Drug Administration (FDA). The claimant, Schuyler Laboratories (Schuyler), argues that the seized articles of drug are exempt from the labeling requirements of the Food, Drug, and Cosmetic Act (Act).

The parties have filed cross-motions for summary judgment pursuant to Fed.R. Civ.P. 56. Rule 56 authorizes summary judgment where no genuine issue as to any material fact exists, and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

This is such a case.

Summary judgment for claimant.

I. Facts

The facts are undisputed. The complaint, filed July 3, 1986, alleges that the Defendant drugs are misbranded under the

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[1] The section states in pertinent part:

> Any article of . . . drug . . . that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of sections 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States . . . within the jurisdiction of which the article is found . . . .

21 U.S.C. § 334(a)(1). All section references herein are to sections of the Act as found in the U.S. Code.

provisions of 21 U.S.C. § 352(f)(1),[2] in that their labels do not bear "adequate directions for use."[3] The complaint further alleges that certain of the drugs are unapproved new animal drugs within the meaning of 21 U.S.C. § 321(w)(3),[4] and, therefore, are adulterated under 21 U.S.C. §§ 360b(a)(1)[5] and 351(a)(5).[6]

On July 9, 1986, the United States Marshal seized approximately 52 lots of drugs at the Schuyler facility in Rushville, Illinois. Schuyler filed a claim for the drugs on July 18, 1986.

Schuyler purchases bulk drugs (active drug ingredients that require further processing before use) for repacking and sale directly and exclusively to veterinarians. Some of the seized articles were in the original containers in which the drugs were

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[2] The section provides in pertinent part: "A drug or device shall be deemed to be misbranded . . . [u]nless its labeling bears (1) adequate directions for use . . ." See endnote 3 for definition of "adequate directions for use."

[3] 21 C.F.R. § 201.5 defines "adequate directions for use" as "directions under which a layman can use a drug safely and for the purposes for which it is intended."

[4] The section states in pertinent part:

> The term "new animal drug" means any drug intended for use of animals other than man, including any drug intended for use in animal feed but not including such animal feed . . . which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug . . . .

21 U.S.C. § 321(w)(3).

[5] The section states in pertinent part:

> A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 351(a)(5) and section 342(a)(2)(D) of this title unless-
>
> (a) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug . . . .

21 U.S.C. § 360b(a)(1).

[6] "A drug or device shall be deemed to be adulterated . . . if it is a new animal drug which is unsafe within the meaning of section 360(b) of this title . . . ." 21 U.S.C. § 351(a)(5).

shipped to Schuyler. The labeling of these products bears shipping information, such as the name and place of business of the manufacturer, packer, or distributor, and the identity of the bulk drug substance. The remaining articles seized had been repacked by Schuyler and bear labels that contain the name "Schuyler Laboratories" and state "for manufacturing, processing, or repacking," and contain the name of the drug. The seized articles are not accompanied by labeling that bears directions for use.

II. Analysis

A. Labeling under § 352(f)(1)

Under 21 U.S.C. § 352(f)(1),

> [a] drug or device shall be deemed to be misbranded--
> ... Unless its labeling bears (1) adequate directions for use; ... *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary *shall* promulgate regulations exempting such drug or device from such requirement. (emphasis supplied)

In response to the *mandatory* proviso of the above quoted section, the Secretary promulgated the following exemption for bulk drugs:

> A drug in a bulk package, except tablets, capsules, or other dosage forms, intended for processing, repacking, or use in the manufacture of another drug shall be exempt from § 502(f)(1) [21 U.S.C. § 352(f)(1)] of the Act if its label bears the statement "Caution: For manufacturing, processing, or repacking" .... But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug ....

21 C.F.R. § 201.122 (1987).

It is the Government's contention that the limitation on the exemption ("But the exemption shall not apply ...") works to take these bulk drugs out of the exemption because the finished articles

form new animal drugs. On the other hand, Schuyler contends that the bulk drugs are exempt and the limitation on the exemption does not come into play because the compounded drugs are not new animal drugs.

1. *The Burden of Proof*

[1]The burden of proof falls on the Government to show by a preponderance of the evidence that: (1) the seized drugs are intended for use in animals; (2) that they do not bear adequate directions for use; and (3) that the drugs were held for sale after shipment in interstate commerce. *See United States v. An Article of Device: "Toftness Radiation Detector,"* 731 F.2d 1253, 1261 (7th Cir.), *cert. denied*, 469 U.S. 882, 105 S. Ct. 249, 83 L.Ed.2d 186 (1984). Since these facts have been admitted by claimant, the Government has carried its burden. Thus, the seized drugs are misbranded unless they fall within one of the exemptions from the requirement. Claimants contend that the drugs fall within the bulk drug exemption of 21 C.F.R. § 201.122 (quoted above).

There is a disagreement among the parties as to whose burden it is to show the applicability or nonapplicability of the exemption. To resolve this issue we are guided by *Toftness*, wherein the Court of Appeals, addressing the misbranding of a prescription device under § 352(f)(1), determined that one claiming an exemption under the misbranding regulations bears the burden of showing its applicability. The Court came to this conclusion after analysis of the statute's structure and application of the general rule that a party claiming entitlement to a statutory exemption bears the burden of proving the entitlement. *See United States v. First City Nat'l Bank*, 386 U.S. 361, 366, 87 S.Ct. 1088, 1092, 18 L.Ed.2d 151 (1967). The *Toftness* court stated:

> [T]he FDA promulgated the regulations . . . and those regulations make prescription devices one of several exemptions to the more general labeling requirements. No purpose justifying this odd structure occurs to us other than the purpose of shifting the burden of proof. By treating the large category of prescription devices under an exemption to the more general requirements,

> the FDA appears to have wanted to make its task somewhat easier by placing on claimants the burden of proving that their device is safe and is actually effective for its intended purposes.
>
> Although this regulatory arrangement may seem strange insofar as it makes prescription devices presumptively misbranded, the [regulatory scheme] is not contrary to either the letter or intent of the statute.

Toftness, 731 F.2d at 1261.

Thus, according to *Toftness*, unless the exemption is contrary to either the letter or intent of the statute, Schuyler must bear the burden of showing the applicability of the exemption.

2. ***Applicability of the Bulk Drug Regulation***

It is axiomatic that for regulations to be valid they "must be consistent with the statute under which they are promulgated." *United States v. Larionoff*, 431 U.S. 864, 873, 97 S.Ct. 2150, 2156, 53 L.Ed. 2d 48 (1977). In *Manhattan General Equip. Co. v. Commissioner*, 297 U.S. 129, 56 S.Ct. 397, 80 L.Ed. 528 (1936), the Court stated: "The power of an administrative officer or board to administer a federal statute and to prescribe rules and regulations to that end is . . . [only] the power to adopt regulations to carry into effect the will of Congress as expressed by statute. A regulation which does not do this, but operates to create a rule out of harmony with the statute, is a mere nullity." *Id.* at 134, 56 S.Ct. at 400, *quoted in Larionoff*, 431 U.S. at 873 n. 12, 97 S.Ct. at 2156 n.12.

In the instant case, the regulation states that bulk drugs such as those at issue are exempt from the § 352(f)(1) labeling requirements *unless* the bulk drug's use will result in a finished product which is a "new drug." However, under the regulation this "new drug" limitation can be avoided if an approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder-in this case the veterinarian.

Thus, the question for this Court is whether the bulk drug exemption regulation is in harmony with the letter and intent of the

statute under which the regulation was enacted. For the reasons given below, the Court finds that the regulation is not in harmony with the legislation.

a. *The Legislative Scheme Generally*

[2] Generally, Congress has shown a reluctance to interfere with the healing arts, of which veterinary medicine is obviously one. Specifically, the legislative history of the Food, Drug, and Cosmetic Act does not support the authority of FDA to meddle in the field of drug compounding done within the scope of the professional practice of medicine-be it veterinary or otherwise.

When the Act became law in 1938, it was clear to the legislators that it was not the purpose of the Act to involve the agency in the practice of healing arts. The committee reports made clear the bill was "not intended as a medical practices act and [would] not interfere with the practice of the healing art[s] . . . ." S.Rep. No. 361, 74th Cong., 1st Sess. 3 (1935), *quoted in Chaney v. Heckler*, 718 F.2d 1174, 1179 n. 13 (D.C.Cir.1983), *rev'd on other grounds*, 470 U.S. 821, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985). The *Chaney* court further stated that "the legislative history makes clear that Congress did not want to limit a physician's ability to treat his patients." *Chaney*, 718 F.2d at 1179 n. 13. As a former chief counsel to the FDA has stated:

> The legislative history of the . . . Act of 1938 is replete with statements that the statute was not intended to regulate the practice of medicine. The man who guided the legislation through the Congress, Senator Royal Copeland, was a physician, and was undoubtedly concerned about interfering with his profession . . . . Through the six years of legislative history the proposed legislation contained the affirmative requirement that every drug must bear adequate directions for use. Not only does the legislative history fail to show a Congressional intent that this be used to restrict the conditions for which physicians might prescribe drugs, but it flatly contradicts any such interpretation. In enacting the

> 1938 Act Congress clearly intended to avoid impinging on the practice of medicine.

Hutt, Regulation of the Practice of Medicine Under the Pure Food & Drug Laws, 33 A. of Food & Drug Officials Q.Bull. 3, 7 & 9 (1969).

In 1962, the Drug Amendments Act, Pub. L. No. 87-781, 76 Stat. 781 (1962), greatly enhanced the FDA's regulation responsibilities. However, some explicit exclusions from that expanded authority uphold the original intent of the Act-that Congress nor the FDA should involve itself in the practice of the healing arts. For example, 21 U.S.C. § 374(a)(2) gave the FDA vast inspection powers with respect to prescription drugs. However, § 374(a)(2)(B) specifically exempted licensed practitioners who prescribe or administer drugs within the scope of their profession. Further, in § 360(a)(1) & (b), Congress defined "manufacture, preparation, propagation, compounding, or processing" for purposes of requiring the registration with the FDA of persons engaging in such activities. Yet, Congress specifically exempted from such registration licensed practitioners who "prescribe or administer drugs . . . and who manufacture, prepare, propagate, compound, or process drugs . . . solely for use in the course of their professional practice." 21 U.S.C. § 360(g)(2). This exemption is of particular interest as we are now concerned with the compounding of drugs by persons professionally licensed to do so. It seems peculiar that Congress would see fit to sanction such an exemption on the one hand, and on the other, permit the FDA to regulate labeling in the way it attempts to here. It makes no sense for Congress to grant this exemption, under § 360(a)(1), if it then takes away the very drugs that would be compounded.

Throughout the Act's history, Congress has shown a consistent pattern of staying out of the regulation of the healing arts. The extent to which the FDA attempts to involve itself in the healing arts here is clearly inconsistent and out of harmony with the statute's intent as manifested by Congress.

b. ***Unreasonableness of the Burden of Proof***

[3] The second reason the Court finds the regulation not to be in harmony with the statute is that it shifts to the claimant an

unreasonable burden to show that the exemption applies. Under the Government's regulatory scheme, for the exemption to apply, the claimant must show one of two things: (1) that the finished product in which the bulk drug is used is not a new drug; or (2) that if it is a new drug, a new animal drug application has been secured.

In the previously discussed case of *Toftness*, the Seventh Circuit expressly sanctioned the structuring of a regulation to shift the burden of an exemption's application to the claimant in a misbranding action. However, one of the grounds upon which the Court based its decision was the fact that the claimant was in a better position to come forward with the evidence which could show applicability of the exemption. In other words, claimant there was in a better position to show that the prescription device worked safely and effectively.[7]

Here, that is not the case. In fact, not only can the claimant not come forward with such evidence, but neither can the Government. Because of the nature of bulk drugs (drugs compounded with other drugs and substances to make a finished product), it is impossible to tell, at this stage, whether the finished product will be a new drug since there is no finished product yet. Thus, the FDA would force the claimant to produce proof which is nonexistent in order to invoke the exemption. This result is unreasonable.

Equally unreasonable is the claimant's option, under exemption regulation, of showing that if a new drug is being produced that a new animal drug application has been secured. Because the claimant has no idea what drug will be produced, he is in no position to secure an application. Second, the expectation that veterinarians should secure a new animal drug application ignores

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[7] The Court stated as its holding on the issue: Because the [claimants] are claiming the application of an exemption to the general labeling requirements, and because they appear to be in the better position to come forward with evidence that the [device] works safely and effectively, we conclude that . . . claimants had the burden of proving that the perscription device exemption applied . . . .

Toftness, 731 F.2d at 1262.

the practical realities of veterinary medicine. To expect an individual veterinarian to subject himself to the many years and millions of dollars involved in the approval process is clearly unrealistic and unreasonable. The veterinarian prescribes and compounds drugs as the need arises in the animals under his care. Such individual use of various drugs does not warrant the filing for a new animal drug application. In fact, the director of the FDA's Center for Veterinary Medicine, Dr. Gerald Guest, testified at a deposition[8] that he was unaware of any veterinarian who has ever obtained a new animal drug approval for a drug to be used in his practice.

In *Ruley v. Nevada Bd. of Prison Comm'rs*, 628 F.Supp. 108 (D.Nev.1986), the Court correctly stated:

> An administrative agency that administers a statute does not have the power to make law; rather, its authority is to adopt regulations to carry into effect the will of the legislature as expressed by the statute. *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213-14, 96 S.Ct. 1375, 1390-91, 47 L.Ed.2d 668 (1976). It follows that the agency may not make a rule or regulation that is out of harmony with or goes beyond the scope of its statutory grant of authority.

Ruley, 628 F.2d at 111; *see also United States v. Richards*, 583 F.2d 491, 495 (10th Cir. 1978) ("the validity of regulations promulgated under an authorizing statute will be sustained [only if] they are 'reasonably related to the purposes of the enabling legislation.'"); *Bates v. United States*, 581 F.2d 575, 580 (6th Cir.1978).

Clearly, for the reasons given above, the regulation at issue is "out of harmony" with the statutory authority and "goes beyond the scope" of it. Congress has, throughout the history of the Act, shown great deference to the autonomy of the healing arts and has left to the states any necessary regulation. The FDA attempts in this cause to establish for the first time that it is empowered to con-

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[8] This deposition was taken in a separate but similar lawsuit pending in the District Court of New Jersey. *United States v. Algon Chemical, Inc.*, No. 87- 1820 (D.N.J. filed May 12, 1987).

trol an integral part of veterinary practice.[9] This is an unacceptable reading of the Act. Veterinarians need the freedom to prescribe and compound drugs according to the needs of its clients and not within the constraints which would be posed by the FDA's reading of the Act. Congress has *never* attempted to handcuff veterinarians in such a way and neither will this Court.

[4] Having found that the agency has overstepped its regulatory authority, the Court must now fashion a remedy. We must read the regulation as consistent with the statute to the extent possible. *See Bencivenga v. Western Pennsylvania Teamsters*, 763 F.2d 574 (3d Cir.1985). The regulation is consistent with the statute to the point of exempting bulk drugs from the general labeling requirements. However, with respect to this claimant-a seller of the bulk drugs to veterinarians-the limitation of the exemption (*i.e.*, that "new drugs" are not exempt) is unreasonable and arbitrary and, therefore, a nullity.

Thus, the Court finds that the exemption, of 21 C.F.R. § 201.122, from the labeling requirements, of 21 U.S.C. § 352(f)(1), does apply to exempt the bulk drugs at issue from the labeling requirements.

B. Applicability of Section 321(w)(3) to the Five Lots

[5] Consistent with the previous finding, the Court holds that the new animal drug provisions of the Act, specifically here § 321(w)(3), are not applicable to the five lots of Defendant articles ampicillin trihydrate, amoxicillin trihydrate, tetracycline HCL, streptomycin sulfate, and penicillin V potassium. This is true be-

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[9] By affidavit, Dr. Robert M. Clack, D.V.M. stated: "If veterinarians were allowed to use only products that FDA approved and at the level that FDA approved them, it would be impossible for us to do our professional work. FDA's approved drugs and approved labeling are not flexible and do not work in the real world of animal disease." The claimant has submitted several other affidavits from veterinarians attesting similarly. While the Court must give deference to the opinion of the regulatory agency, it also gives much credence to the opinions of learned veterinarians who are physically engaged in the practice of veterinary medicine and who must cope with the day to day problems in the field, as opposed to FDA officials who are not currently engaged in such day to day, hands on activity.

cause these are not finished dosage forms of the drugs. It is clear from the statutory scheme that Congress only intended the new drug provisons to apply to finished dosage forms.

In 21 U.S.C. § 321(w)(3), Congress defines the term new animal drug as "any drug *intended for use* in animals other than man, including any drug intended for use in animal feed but not including such animal feed . . . which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof. . . ." (emphasis added) Here, the drugs seized are not in finished dosage form and thus are not "intended for use" in animals in their present form. Thus, they are not "new animal drugs" as Congress used that term in the statute.[10] *Cf. United States v. Generix Drug Corp.*, 460 U.S. 453, 457, 103 S.Ct. 1298, 1300, 75 L.Ed.2d 198 (1983) (wherein the court held that an entire generic drug product was subject to new drug approval statute and not simply the active ingredient in the generic drug).

III. Conclusion

In summary, the Court finds (1) that the bulk drug exemption of 21 C.F.R. § 201.122 applies to bulk drugs supplied to veterinarians for use within the scope of the practice of their profession, and (2) the new animal drug definition of 21 U.S.C. § 321(w)(3) does not apply to such drugs.

Ergo, claimant's motion for summary judgment is ALLOWED. Conversely, Plaintiff's motion for summary judgment is DENIED. In accord with this ruling, the United States Marshal is hereby ordered to return the Defendant articles to the claimant.

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[10] It is interesting to note that review of the United States Code Annotated reveals that every lawsuit brought by the United States under § 321 involving new drugs or new animals drugs has involved a finished dosage drug. Clearly, the FDA is attempting to break into new areas of regulation with this as a test case.

JUDGMENT -- ORAL ARGUMENT

UNITED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604

July 27, 1988

Before

Hon. Frank H. Easterbrook, Circuit Judge
Hon. Daniel A. Manion, Circuit Judge
Hon. Jesse E. Eschbach, Senior Circuit Judge

UNITED STATES OF AMERICA,
Plaintiff-Appellant,

No. 88-1233

vs.

9/1 KG. CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, et al.,
Defendants-Appellees.

Appeal from the United States District Court for the Central District of Illinois, Springfield Division.
No. 86-C-3201
RICHARD MILLS, Judge

This cause was heard on the record from the United States District Court for the Central District of Illinois, Springfield Division, and was argued by counsel.

On consideration whereof, IT IS ORDERED AND ADJUDGED by this Court that the judgment of the said District Court in this cause appealed from be, and the same is hereby, REVERSED, with costs, in accordance with the opinion of this Court filed this date.

UNITED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604

September 6, 1988

Before

Hon. Frank H. Easterbrook, Circuit Judge
Hon. Daniel A. Manion, Circuit Judge
Hon. Jesse E. Eschbach, Senior Circuit Judge

UNITED STATES OF AMERICA,
Plaintiff-Appellant,

No. 88-1233

vs.

9/1 KG. CONTAINERS, MORE OF LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE,
Defendants-Appellees.

Appeal from the United States District Court for the Central District of Illinois, Springfield Division.
No. 86-3201
Richard Mills, Judge

ORDER

Defendants-Appellees filed a petition for rehearing and suggestion of rehearing en banc on August 10, 1988. No judge in regular active service has requested a vote on the suggestion of rehearing en banc, and all of the judges on the panel have voted to deny rehearing. The petition for rehearing is therefore DENIED.

§ 321. Definitions; generally

For the purposes of this chapter--

(w) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,--

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions; or

(3) which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug on the grounds that (A) the requirement of certification of batches of such drug, as provided for in section 360b(n) of this title, is not necessary to insure that the objectives specified in paragraph (3) thereof are achieved and (B) that neither subparagraph (1) nor (2) of this paragraph (w) applies to such drug.

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded--

Directions for use and warnings on label

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological con-

ditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this subsection, as applied to any drug or device,is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

§ 360b. **New animal drugs--Unsafe new animal drugs and animal feed containing such drugs; conditions of safety; exemption of drugs for research**

(a)(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 351(a)(5) and section 342(a)(2)(D) of this title unless--

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug,

(B) such drug, its labeling, and such use conform to such approved application, and

(C) in the case of a new animal drug subject to subsection (n) of this section and not exempted therefrom by regulations it is from a batch with respect to which a certificate or release issued pursuant to subsection (n) is in effect with respect to such drug.

A new animal drug shall also be deemed unsafe for such purposes in the event of removal from the establishment of a manufacturer, packer, or distributor of such drug for use in the manufacture of animal feed in any State unless at the time of such removal such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee--

(i) is the holder of an approved application under subsection (m) of this section; or

(ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of an approved application under subsection (m) of this section.

(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed, be deemed unsafe for the purposes of section 351(a)(6) of this title unless--

(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such drug, as used in such animal feed,

(B) there is in effect an approval of an application pursuant to subsection (m)(1) of this section with respect to such animal feed, and

(C) such animal feed, its labeling, and such use conform to the conditions and indications of use published pursuant to subsection (i) of this section and to the application with respect thereto approved under subsection (m) of this section.

(3) A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of section 351(a)(5) or (6) of this title if such article is for investigational use and conforms to the terms of an exemption in effect with respect thereto under subsection (j) of this section.

Filing application for uses of new animal drugs; contents

(b) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe and effective for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter)

of animals to which such drug (directly in or on animal feed) is intended to be administered, as the Secretary may require; (6) specimens of the labeling proposed to be used for such drug,or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant; (7) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and (8) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe.

§ 201.122 Drugs for processing, repacking, or manufacturing

A drug in a bulk package, except tablets, capsules,or other dosage unit forms, intended for processing, repacking, or use in the manufacture of another drug shall be exempt from section 502(f)(1) of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking"; and, if in substantially all dosage forms in which it may be dispensed it is subject to section 503(b)(1), the statement "Caution: Federal law prohibits dispensing without prescription". This exemption and the exemption under § 201.120 may be claimed for the same article. But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:

(a) An approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder by persons named in the application, and, for a new drug substance, the export of it by such persons under § 314.410 of this chapter; or

(b) If no application is approved with respect to such new drug or new animal drug, the label statement "Caution: For

manufacturing, processing, or repacking" is immediately supplemented by the words "in the preparation of a new drug or new animal drug limited by Federal law to investigational use," and the delivery is made for use only in the manufacture of such new drug or new animal drug limited to investigational use as provided in § 312.1 or § 511.1 of this chapter; or

(c) A new drug application or new animal drug application covering the use of the drug substance in the production and marketing of a finished drug product has been submitted but not yet approved or disapproved, the bulk drug is not exported, and the finished drug product is not further distributed after it is manufactured until after the new drug application or new animal drug application is approved.

UNITED STATES COURT OF APPEALS
For the Seventh Circuit
Chicago, Illinois 60604

September 30, 1988

Before

Hon. Frank H. Easterbrook, Circuit Judge

UNITED STATES OF AMERICA,
Plaintiff-Appellant,

No. 88-1233

vs.

9/1 KG. CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, et al.,
Defendants-Appellees.

Appeal from the United States District Court for the Central District of Illinois, Springfield Division.
No. 86 C 3201
Judge Richard Mills

This matter comes before the court for its consideration of the following documents:

1. "APPELLEES' MOTION TO STAY THE MANDATE" filed herein on September 13, 1988, by counsel for the appellees.
2. "GOVERNMENT'S MEMORANDUM IN OPPOSITION TO APPELLEES' MOTION TO STAY THE MANDATE" filed herein on September 23, 1988, by counsel for the appellant.

On consideration thereof,

IT IS ORDERED that the mandate in this appeal shall be STAYED to and including October 12, 1988. If during the period of the stay, the clerk of the Supreme Court of the United States notifies the clerk of this court that the defendants have filed a petition for a writ of certiorari, the stay shall continue until final disposition of the petition by the Supreme Court. No bond shall be required. Accordingly,

IT IS ORDERED that the APPELLEES' MOTION TO STAY THE MANDATE is GRANTED.

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,

Plaintiff,

Civil Action No. 87-1820

v.

ALGON CHEMICAL INC., a corporation;
and EDWARD LATINSKY, an individual,

Defendant.

APPEARANCES:

SAMUEL A. ALITO, JR., United States Attorney
By: Kevin J. McKenna, Assistant U.S. Attorney
Federal Building
970 Broad Street
Newark, NJ 07102

and

THOMAS SCARLETT, Chief Counsel
By: Richard E. Geyer, Associate Chief Counsel
for Veterinary Medicine
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(Attorneys for Plaintiff)

CRUMMY, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE
By: Robert A. Recio, Esquire
One Gateway Center
Newark, New Jersey 07102-5311

and

HYMAN, PHELPS & McNAMARA, P.C.
By: James R. Phelps, Esquire
Robert A. Dormer, Esquire
A. Wes Siegner, Jr., Esquire
1120 G Street, N.W., Suite 1040
Washington, D.C. 20005
(Attorneys for Defendants)

BISSELL, *District Judge*

These cross-motions arise out of a Complaint filed on May 12, 1987 by the United States of America ("United States") against Algon Chemical, Inc. ("Algon") and Edward B. Latinsky, President of Algon. In this cause, the United States sought preliminary and permanent injunctive relief against the distribution in interstate commerce of 13 lots of bulk drugs[1] in contravention of § 331(a), (c)[2] of the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.*, and temporary, preliminary and permanent injunctive relief against the receipt and distribution of similar drugs in future contravention of the Act. The Court ordered the defendants to show cause as to why an order should not be entered issuing a preliminary and permanent injunction restraining them from violation of the Act. After oral argument on May 28, 1987, the Court, finding no material issue of fact, dismissed plaintiff's application for preliminary injunction and *sua sponte* ordered the parties to file cross-motions for summary judgment.

Plaintiff's Complaint alleges that the drugs are not labeled with adequate directions for use and are, therefore, misbranded within the meaning of 21 U.S.C. § 352(f)(1). Additionally, plaintiff alleges that one of the lots of drugs, penicillin, is an unapproved new animal drug within the meaning of 21 U.S.C. § 321(w)(3),[3] and therefore is adulterated under 21 U.S.C. § 360 (a)(1)(A)[4] and

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[1] The drugs are bulk drugs intended for further processing for use on animals. They include five lots of dimetridazole; two lots each of levamisole and nitrofurazone; and one lot each of penicillin, sulfamethazazole, lincomycin and oxytetracycline.

[2] Title 21 U.S.C. § 331: The following acts and the causing thereof are hereby prohibited: (a) [t]he introduction or delivery for introduction into interstate commerce of any ... drug ... that is adulterated or misbranded. ... (c) [t]he receipt in interstate commerce of any ... drug ... that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

[3] Plaintiff's Complaint states "penicillin, is adulterated within the meaning of 21 U.S.C. § 351(a)(5) in that it is a new animal drug within the meaning of 21 U.S.C. § 321(w)(1)." The correct section, 21 U.S.C. § 321(w)(3), is cited in Plaintiff's Brief at p. 10.

§ 351(a)(5).[5] The United States brings this proceeding under 21 U.S.C. § 332(a) which vests the United States District Courts with jurisdiction to enjoin and restrain violations of the Act.

The defendant, Algon, argues that the 13 lots of drugs are exempt from the labeling requirements of § 352(f)(1) of the Act by virtue of an exempting regulation, 21 C.F.R. § 201.122. Additionally, defendant argues that the same exempting regulation serves to make § 321(w)(3) inapplicable to the seized penicillin.

Presently before the Court are cross-motions for summary judgment pursuant to Fed. R. Civ. P. 56. On a motion for summary judgment, "[t]he judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The parties, in moving for summary judgment, have agreed that there exist no genuine issues of material fact.[6] The Court will proceed therefore, upon consideration of the pleadings and affidavits submitted, to determine which party is entitled to judgment as a matter of law.

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[4] "A new animal drug shall, with respect to any particular use or intended use ... be deemed unsafe for the purposes of [351(a)(5)] ... unless -- (A) there is in effect an approval of an application filed ... with respect to such use or intended use of such drug." 21 U.S.C. § 360(b)(1)(A).

[5] "A drug ... shall be deemed to be adulterated -- if it is a new animal drug which is unsafe within the meaning of section [360(b)]." 21 U.S.C. § 351(a)(5).

[6] Each party has submitted conflicting statements from practicing veterinarians attesting to (1) the necessity of having access to bulk drugs for successful practice, and (2) the public health risk posed by the use of these drugs. However, these statements do not raise material issues in that they do not address the questions of whether there have been violations of the Food, Drug and Cosmetic Act or whether any alleged violation would continue absent an injunction. *See United States v. Sumitomo Shoji, New York, Inc.*, 534 F.2d 320, 324 (C.C.P.A. 1976) (where an issue of fact is not relevant to the controlling legal question, it is not material so as to preclude summary judgment.)

THE FACTS

Algon has been engaged in receiving and selling in interstate commerce bulk pharmaceutical and chemical supplies for approximately eight years. Drugs that are in bulk form require further processing before actual use. The 13 lots of bulk drugs in question were purchased by Algon after importation into the United States by ICC Industries, and were stored by the NBC Warehouse and Storage Co. in Garfield, New Jersey. These bulk drugs were intended solely for the use of veterinarians in the practice of veterinary medicine. To prevent Algon from shipping the drugs, the Food and Drug Administration ("FDA") requested that the State of New Jersey embargo the drugs under state law until the FDA could obtain relief in federal court.[7] The drugs were placed under embargo beginning September 3, 1986.

Prior to imposition of the embargo, Algon shipped portions of the 13 lots to, among others, Schuyler Laboratories, Rushville, Illinois and Brinton Veterinary Clinic, Willmar, Minnesota. [8] Schuyler, Algon's principal customer, resells the drugs to veterinarians.[9] None of the parties involved -- Algon, Schuyler, Borge and their veterinarian consignees -- hold FDA approvals for use of the drugs.

Two of the embargoed articles were in containers bearing cautionary labels stating "[t]o be used only for manufacturing, processing or repacking." The remaining articles bore labeling indicating only the name of the drug and its origin. None of these drug items were accompanied by labeling that indicated directions for use.

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[7] The FDA sought state embargo because the Act does not provide for administrative detention. Plaintiff's Brief, p. 5 n. 3. Approximately $300,000 worth of bulk chemicals have been embargoed by the State of New Jersey.

[8] Before the embargo Algon also sold a lot of dimetridazole to Borge Laboratories which in turn sold portions of the lot to two veterinary clinics.

[9] The government seized several lots of drugs owned by Schuyler under 21 U.S.C. § 334. The case was litigated in favor of Schuyler. *See United States v. 9/1 KG Containers . . . an Article of Drug for Veterinary Use*, 674 F. Supp. 1344 (C.D. Ill. 1987).

THE LAW

A. Labeling Under § 352(f)(1).

In its Complaint, plaintiff alleges that defendant introduced or delivered for introduction into interstate commerce drugs which were misbranded within the meaning of 21 U.S.C. § 352(f)(1). Section 352 provides that:

> [a] drug ... shall be deemed to be misbranded ...
>
> (f) [u]nless its labeling bears (1) adequate directions for use; ... *Provided*, that where any requirement of clause (1) of this paragraph, as applied to any drug ... is not necessary for the protection of the public health, the Secretary *shall* promulgate regulations exempting such drug ... from such requirement.

(Emphasis supplied). The Secretary promulgated an exemption for bulk drugs in response to the mandatory proviso of § 352(f)(1):

> A drug in a bulk package, except tablets, capsules, or other dosage unit forms, intended for processing, repacking,or use in the manufacture of another drug shall be exempt from section 502 (f)(1) [21 U.S.C. § 352(f)(1)] of the act if its label bears the statement"Caution: For manufacturing, processing, or repacking"; ... But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:
>
> (a) [a]n approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder ...

21 C.F.R. § 201.122.

The limitation in 21 C.F.R. § 201.122 indicates that labeling requirements of 21 U. S. C. § 352(f)(1) are not suspended if a bulk drug is to be used in a finished article that is a new (animal) drug unless an approved new animal drug application covers the production and delivery of the drug substance to the application holder.

Defendant contends that its bulk drug materials,when shipped, are labeled "for manufacturing, processing or repacking" in conformity with the language prescribed in 21 C.F.R. § 201.122 and are therefore exempt from the labeling requirements because they are used by veterinarians to compound finished articles which are unapproved new animal drugs. The issue to be decided, therefore,is whether the exception to the exemption in 21 C.F.R. § 201.122 applies to the defendant in this case.

1. The Burden of Proof.

Plaintiff contends that defendant has the burden of proving that its bulk drugs are exempt from the labeling requirements of 21 U.S.C. § 352(f)(1) and that defendant cannot meet this burden. In *United States v. An Article of Device ... Toftness Radiation Detector*, 731 F.2d 1253(7th Cir. 1984), the court dealt with a similar situation in which defendant was relying on exemptions found in a series of regulations to remove it from the labeling requirements of 21 U.S.C. § 352(f)(1). After examining the language of the statute and appropriate regulations, the court concluded that the "party claiming entitlement to a statutory exemption bears the burden of proving the entitlement * * *unless placing the burden of proof [on the defendant] would be contrary to the [letter and intent] of the Act." *Id.* at 1260, 1261. The precise question for this Court is whether the exception to the exemption in 21 C.F.R. § 201.122 is consistent with the letter and intent of the Act under which it was enacted, thus requiring the defendant to prove that its bulk drugs are entitled to be exempt from the labeling requirements of § 352(f)(1).

2. The Legislative Scheme

The Food, Drug and Cosmetic Act was enacted in 1938, after years of deliberation. The legislative history of the Act demonstrates that Congress had no intention through passage of this Act to interfere with the practice of the healing arts[10] and that

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[10] S. Rep. No. 361, 74th Cong., 1st Sess., 3 (1935). *See Chaney v. Heckler*, 718 F.2d 1174, 1179 n. 13 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985).

all the healing arts "licensed by law in the various states"should be accorded this independence.[11] The Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat 781 (1962), expanded the FDA's authority in carrying out the intent of the Act, however, certain notable exclusions from this expanded authority indicated Congress' intent that the FDA should not exercise the same type of control over the healing arts. Title 21 U.S.C. §374(a)(1)(B) empowers the FDA to"inspect ... such factory, warehouse, establishment, or vehicle ... in which prescription drugs ... are manufactured ... (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs ... are adulterated or misbranded within the meaning of this Act." Title 21 U.S.C. § 374(a)(2) states, however, that "[t]he provisions ... of this subsection shall not apply to -- ... (B) practitioners licensed by law to prescribe or administer drugs ... and who manufacture, prepare, propagate, compound, or process drugs ... solely for use in the course of their professional practice." Similarly, 21 U.S.C. § 360(b) requires that "every person ... engaged in the manufacture, preparation, propagation, compounding or processing of a drug or drugs ... register with the Secretary his name, [and] places of business." Once again, "practitioners licensed by law to prescribe or administer drugs ... and who manufacture, prepare, propagate, compound, or process drugs ... solely for use in the course of their professional practice" are exempt from the registration requirement. 21 U.S.C. § 360(g)(2). These exclusions apply to veterinarians as well as other practitioners of the healing arts.

In 1968 Congress amended the Food, Drug and Cosmetic Act with Animal Drug Amendments, Pub. L. No. 90-399, 82 Stat. 343 (Codified as 21 U.S.C. § 360b (1982)), intended to "merely consolidate provisions under existing law."[12] The amendments did not add much "new" law, but simply drew together in § 360b the requirements for drugs and certifiable antibiotics which had previously been scattered throughout the existing Act. The only new

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[11] S. Rep. No. 361, 74th Cong., 1st Sess., 5 (1935).

[12] S. Rep. No. 1308, 90th Cong., 2d Sess. 1, *reprinted in* 1968 U.S. Code Cong.& Admin. News 2608.

section was that dealing with drugs in feed, or the medicated feed section. Congress had the opportunity to alter substantially the provision of the Act pertaining to the regulation of animal drugs; however, it chose merely to consolidate the existing provisions into a more efficient format. There is nothing in the legislative history of the Animal Drug Amendments of 1968 indicating that they were intended to have any impact upon the practice of veterinary medicine.

In the instant case, the regulation in question exempts bulk drugs from the labeling requirements of 21 U.S.C. § 352(f)(1) unless the bulk drug will be used to produce a finished article which is a new drug. The "new drug" limitation can be avoided only if a new animal drug application covers the production and delivery of the drug to "the application holder." Since these bulk drugs are being produced for and delivered to veterinarians, the regulation, in effect, requires that veterinarians must be holders of new animal drug approvals. In order to apply for and become holders of new animal drug approvals, veterinarians would have to comply with registration and inspection provisions of the Act from which they have been expressly exempted. This is an unreasonable expectation given Congress' consistent approach of staying out of the regulation of the healing arts.

"The validity of regulations promulgated under an authorizing statute will be sustained so long as they are 'reasonably related to the purposes of the enabling legislation'." *United States v. Richards*, 583 F.2d 491, 495 (10th Cir. 1978) (quoting *Thorpe v. Housing Authority of the City of Durham*, 393 U.S. 268, 280-81 (1969)).

United States v. 911 KG Containers ... Article of Drug for Veterinary Use, 674 F. Supp. 1344 (C.D. Ill. 1987),[13] presenting a fact pattern very similar to the case at bar, deals directly with the validity of 21 C.F.R. § 201.122. The court stated that it "makes no sense for Congress to grant [an exemption from registration for

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[13] An opinion was rendered in favor of defendant on December 8, 1987. The court subsequently granted the government's motion for a stay of judgment pending appeal to the United States Court of Appeals for the Seventh Circuit.

those who prescribe or administer drugs and who compound, or process drugs solely for use in the course of their professional practice] if it then takes away the very drugs that would be compounded." *Id.* at 1349. The court found the regulation to be clearly "inconsistent and out of harmony with the statute's intent as manifested by Congress." *Id.* at 1349. Furthermore, the Court found that requiring the defendant to carry the burden of showing a regulatory exemption applies to its situation was unreasonable. In order to benefit from the labeling exemption defendant would have to demonstrate that "(1) the finished product in which the bulk drug is used is not a new drug; or (2) that if it is a new drug, a new animal drug application has been secured." *Id.* at 1349. First, the court noted that neither the plaintiff nor the defendant would be able to show that the finished product was not a new drug because, up until the time of compounding by the individual veterinarian, there was no finished product. Second, defendant could not possibly apply for a new drug approval because he has no idea what drug will be produced when veterinarians compound a finished product from bulk drugs. Finally, to require veterinarians to apply for new drug approvals is simply unrealistic and inconsistent with Congress' intent to stay out of the regulation of veterinary medicine. After noting that a regulation must be read as consistent with the statute,[14] the court concluded that the "regulation [was] consistent with the statute to the point of exempting bulk drugs from the general labeling requirements. However, ... the limitation of the exemption (*i.e.*, that 'new drugs' are not exempt) [was] unreasonable and arbitrary and therefore, a nullity." *Id.* at 1350.[15]

The present case is nearly identical to *United States v. 9/1 KG Containers* in that the United States alleges that defendant's drugs are misbranded under the provisions of 21 U.S.C. § 352 (f)(1) and defendant relies on the exempting provisions of 21 C.F.R. § 201.122 to remove its bulk drugs from the labeling requirements

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[14] *See Bencivenga v. Western Pa. Teamsters*, 763 F.2d 574 (3d Cir. 1985).

[15] *See Fowler v. Gage*, 301 F.2d 775, 778-79 (10th Cir. 1962). A portion of a regulation may be severed so long as the remainder of the regulation is valid.

of § 352(f)(1). Here, as in that case, to require defendant to show that the finished product in which its bulk drugs are to be used is *not* a new drug; or to show that if the finished product is a new drug, a new animal drug application has been secured by the veterinarian receiving the bulk drug, is unreasonable. The Court finds that 21 C.F.R. § 201.122 places upon the defendant the impossible burden of demonstrating that the exemption applies to its bulk drugs. The Court also finds that the exceptions to the basic exemption are not consistent with the statute under which this regulation was promulgated. Therefore, in order to give a reasonable meaning to the exempting regulation, consistent with the Act, the Court finds that only that portion which exempts bulk drugs from the labeling requirements of 21 U.S.C. § 352(f)(1) applies to bulk drugs supplied for use in the practice of veterinary medicine.

B. Applicability of § 321(w)(3) to the Bulk Drug Penicillin.

Plaintiff alleges that one of the drug lots, penicillin, is an unapproved new animal drug within the meaning of 21 U.S.C. § 321(w)(3), and therefore is adulterated under 21 U.S.C. § 360(a)(1) and § 351(a)(5). Defendant contends that all § 321(w)(3) does is to make penicillin subject to the new animal drug requirements when it is manufactured in a form suitable for commercial purposes. The issue to be decided then is whether *bulk* penicillin is in a form intended for use in animals so as to be an new animal drug subject to the provisions of § 360(a)(1) and § 351(a)(5).

Section 321(w)(3) provides that "[t]he term 'new animal drug' means any drug *intended for use for animals* other than man ... which drug is composed wholly or partly of any kind of penicillin." (Emphasis supplied). The language of the statute clearly indicates that the term "new animal drug" applies only to drugs which are manufactured in a finished dosage form and not to bulk ingredients used in compounding by veterinarians. Here, the drugs under embargo are not in finished dosage forms (*e.g.*, capsules, tablets) and are not "intended for use" in their present form. Instead, they are intended solely for the use of veterinarians who will

compound them into medicines to be used in their practices. "Thus they are not 'new animal drugs' as Congress used that term in the statute."[16] For this reason, the Court finds that the new animal drug provisions of § 321(w)(3) are not applicable to the embargoed lot of penicillin; therefore, it is not adulterated within the meaning of 21 U.S.C. § 360(a)(1)(A) and § 351(a)(5).

Although plaintiff's Complaint specifically cites only penicillin as being adulterated under the provisions of 21 U.S.C. § 321(w)(3), the Court finds that none of these bulk drugs are "intended for use" in animals because they are not in final dosage forms, and are therefore not "adulterated."

CONCLUSION

The Court finds that the bulk drug exemption to 21 U.S.C. § 352(f)(1)provided in 21 C.F.R. § 201.122 applies to the bulk drugs which are the subject of the present action and are supplied to veterinarians solely for compounding into medicines used in their practices, and that the "new animal drug" provision of 21 U.S.C. § 321(w)(3) does not apply to the embargoed lot of penicillin. Accordingly, the Court grants defendant's motion for summary judgment.

/s/ John W. Bissell
John W. Bissell
United States District Judge

DATED: April 12, 1988

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[16] *United States v. 9/1 KG Containers ... Articles of Drug for Veterinary Use, supra*, held that it was clear from the "statutory scheme that Congress only intended the new drug provisions to apply to finished dosage forms." 674 F. Supp. at 1351.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,

Plaintiff,

Civil Action No. 87-1820

v.

ALGON CHEMICAL INC., a corporation; and EDWARD LATINSKY, an individual,

Defendants.

ORDER

For the reasons set forth in the Court's Opinion filed herewith,

It is on this 12th day of April, 1988,

ORDERED that defendants' motion for summary judgment be and it hereby is granted, and this action be and it hereby is dismissed, with prejudice and with costs.

/s/ John W. Bissell
John W. Bissell
United States District Judge

Supreme Court, U.S.
FILED
JAN 9 1989
JOSEPH F. SPANIOL, JR.
CLERK

No. 88-614

In the Supreme Court of the United States

OCTOBER TERM, 1988

9/1 KG CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, AND SCHUYLER LABORATORIES, INC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

CHARLES FRIED
Solicitor General
JOHN R. BOLTON
Assistant Attorney General
ROBERT S. GREENSPAN
LAWRENCE G. MCDADE
Attorneys
Department of Justice
Washington, D.C. 20530
(202) 633-2217

THOMAS SCARLETT
Chief Counsel
RICHARD E. GEYER
Attorney
Food and Drug Administration
Rockville, Maryland 20857

QUESTION PRESENTED

A regulation promulgated under the Federal Food, Drug, and Cosmetic Act provides in relevant part that a drug in a bulk package shall not be exempt from the labeling requirements of the Act if it is intended for use in the manufacture of a "new drug" unless certain requirements are met. The question presented is whether that regulation is valid as applied to bulk packages of drugs to be distributed in interstate commerce to veterinarians.

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In the Supreme Court of the United States

OCTOBER TERM, 1988

No. 88-614

9/1 KG CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, AND SCHUYLER LABORATORIES, INC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-10a) is reported at 854 F.2d 173. The opinion of the district court (Pet. App. 11a-24a) is reported at 674 F. Supp. 1344.

JURISDICTION

The judgment of the court of appeals was entered on July 27, 1988. A petition for a rehearing was denied on September 6, 1988 (Pet. App. 26a). The petition for a writ of certiorari was filed on October 12, 1988. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. To protect the food supply and the public against potentially dangerous residual effects from the use

on animals of drugs that have not been proved safe and effective, and to protect the animals themselves, the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. (& Supp. IV) 301 *et seq.*, establishes a system of premarketing approval for new animal drugs. 21 U.S.C. 360b; *Tri-Bio Laboratories, Inc.* v. *United States,* 836 F.2d 135, 138 (3d Cir. 1987), cert. denied, No. 87-1804 (Oct. 3, 1988); *United States* v. *An Article of Drug Consisting of 4,680 Pails* (*Neo-Terra*), 725 F.2d 976, 978 (5th Cir. 1984).[1] With certain exceptions not relevant here, a drug is a "new animal drug" unless it is generally recognized by qualified experts as safe and effective for the conditions prescribed, recommended, or suggested in its labeling. 21 U.S.C. 321(w)(1); *Neo-Terra,* 725 F.2d at 980. The FDCA prohibits the introduction into interstate commerce of a new animal drug unless the Food and Drug Administration (FDA) has approved a new animal drug application (NADA) for it. 21 U.S.C. 360b(a)(1)(A); *Neo-Terra,* 725 F.2d at 980. The predistribution approval requirement applies equally to prescription and over-the-counter drugs. The FDA ordinarily approves only finished drug products that are formulated and packaged for use essentially "as is" by the ultimate user, whether a practitioner or layman; approval is not granted for active bulk ingredients per se. See 21 C.F.R. 514.1(b)(4); cf. *United States* v. *Generix Drug Corp.*, 460 U.S. 453 (1983). Unapproved new animal drugs are deemed by the Act to be adulterated and are subject to seizure. 21 U.S.C. 360b(a)(1)(A), 351(a)(5), 331-334.

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[1] Section 201(g) of the FDCA defines "drugs" to include veterinary drugs. 21 U.S.C. 321(g). The Act also establishes a similar system for human drugs. 21 U.S.C. (& Supp. IV) 355; *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 613 (1973).

The sponsor of a new animal drug, ordinarily a drug or animal feed company, has the burden of proving that a drug meets all criteria for approval. *United States* v. *Colahan,* 811 F.2d 287, 292 (6th Cir. 1987), cert. denied, No. 86-1783 (Oct. 5, 1987); *Rhone-Poulenc, Inc., Hess & Clark Division* v. *FDA,* 636 F.2d 750, 752 (D.C. Cir. 1980). To obtain the FDA's approval, the sponsor must prove the safety and effectiveness of the drug on the basis of scientific evidence, including adequate and well-controlled clinical studies. See, *e.g., Warner-Lambert Co.* v. *Heckler,* 787 F.2d 147, 150-151 (3d Cir. 1986). If a drug is to be used in food-producing animals, the sponsor must prove that use of the drug will not leave harmful drug residues in meat, milk, or eggs. 21 U.S.C. 360b(b)(1), (7), and (8), 360b(d) (1)(A), (B), and (H), and (d)(2). As part of the NADA approval process, the FDA determines under what conditions a drug may be used, *e.g.,* whether it may be administered only to animals that do not become a part of the food supply, and whether it may be marketed over-the-counter or must be restricted to prescription use. The conditions of use must be specified in the labeling of the drug. See, *e.g.,* 21 U.S.C. 360b(b)(6) and (d).[2]

b. Congress has required that all animal drugs marketed in interstate commerce bear "adequate directions for use." 21 U.S.C. 352(f)(1). This labeling requirement applies to all drugs, including "bulk drugs," *i.e.,* drugs intended for use as components of finished drug products. 21 U.S.C. 321(g)(1)(D). Drugs not properly labeled are "deemed to be misbranded" as a matter of law, 21 U.S.C. 352, and are subject to seizure and other regulatory action. 21 U.S.C. (& Supp. IV) 331-334.

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[2] The FDA publishes in the Code of Federal Regulations the conditions under which an approved new animal drug may be used. See 21 C.F.R. Pt. 500 *et seq.*

A proviso to 21 U.S.C. 352(f) authorizes the FDA to exempt a drug from the labeling requirement when imposition of the requirement is "not necessary for the protection of the public health." 21 U.S.C. 352(f); see *United States* v. *Ellis Research Laboratories, Inc.*, 300 F.2d 550, 552 (7th Cir.), cert. denied, 370 U.S. 918 (1962) ("Unless the [article] falls within the scope of the exemption in the regulations * * *, it is not exempt from [the] labeling requirement[]."). [3] Thus, the question of an exemption turns, in the first instance, on the FDA's scientific judgment as to whether and under what conditions adequate directions for use are unnecessary for the public health. Pet. App. 4a-5a. [4]

Because bulk drugs are not intended for use without further processing, the FDA has determined that under certain circumstances it is unnecessary for them to bear adequate directions for use. In 1952, the FDA adopted a regulation for such drugs, 21 C.F.R. 201.122 (the labeling regulation). Under that regulation, bulk drugs can be exempted from the requirement of 21 U.S.C. 352(f)(1) if they are intended for processing, repacking, or use in the manufacture of another drug, and are labeled accordingly. By its terms, however (and with certain exceptions not relevant here), the exemption does not apply to a bulk drug intended for use in a finished drug product that must itself be approved by the FDA, but does not yet have that

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[3] Although *Ellis Research Laboratories* and several other cases cited in this brief concerned medical devices, not drugs, those cases are fully applicable here, since 21 U.S.C. 352(f) imposes the same labeling requirement on drugs as on devices.

[4] The FDA has the authority to establish conditions on the grant of an exemption from the labeling requirement. See *United States* v. *El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951) (prescription drugs); *Arner Co.* v. *United States*, 142 F.2d 730, 736 (1st Cir.), cert. denied, 323 U.S. 730 (1944) (bulk drugs).

approval, *i.e.*, the finished drug product must not be an unapproved "new drug" or "new animal drug." Such a finished drug would be adulterated under the FDCA, and it could not bear adequate directions for use or qualify for an exemption from that requirement. Thus, a bulk drug supplier who wants to take advantage of the labeling exemption must identify a specific NADA approval for the use of the bulk drug and may deliver the drug only to the application holder. 21 C.F.R. 201.122(a). See also 21 C.F.R. 514.1(b)(5). The labeling regulation applies to all bulk drugs. It does not exempt bulk drugs that will be manufactured into an unapproved new animal drug by a veterinarian, and no other regulation provides such an exception.

2. a. On July 3, 1986, the United States filed this civil seizure action under the FDCA, 21 U.S.C. 334, to condemn 52 lots of bulk drugs in the possession of petitioner Schuyler Laboratories, Inc. (hereinafter petitioner). Pet. App. 2a. The drugs were being held by Schuyler for sale to veterinarians, who would compound them into finished drug products for use in treating animals.[5] The complaint alleged that all 52 lots of the bulk drugs were misbranded because they did not bear adequate directions for use, as required by 21 U.S.C. 352(f)(1).[6]

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[5] "Compounding" refers to the steps taken to prepare a finished drug product from an active ingredient. An example is the preparation of an injectable drug from an active ingredient in powder form. See 50 Fed. Reg. 27018 (1985).

[6] The complaint also alleged that five lots were adulterated since they consisted of certifiable antibiotic animal drugs that could not be marketed without the FDA's approval (21 U.S.C. 321(w)(3), 351(a)(5), 360b(n)) and because neither Schuyler nor any of its customers had obtained the requisite approval. The only issue in this respect was whether the antibiotic drugs were intended for animal use in their bulk form, because there was no dispute that the drugs had not

There was no dispute that the drugs failed to bear adequate directions for use; in fact, the drugs bore no directions at all. Pet. App. 3a, 16a. The only question involved the applicability of the FDA's labeling exemption, 21 C.F.R. 201.122, to the bulk drugs, and the validity of that regulation as applied. Schuyler claimed that the regulation was invalid as applied to the seized drugs, on the ground that it impermissibly regulated the practice of veterinary medicine.

b. The district court granted Schuyler's motion for summary judgment. Pet. App. 14a-24a. The court held that the drugs were not misbranded since, in the court's view, the regulation was invalid insofar as the denial of an exemption applied to the distribution of a bulk drug to a veterinarian. *Id.* at 19a-23a. The court held that portion of the regulation invalid as applied on the ground that the FDA cannot require that drugs compounded by veterinarians be subject to approval by the agency. *Id.* at 19a-20a, 22a-23a.

c. The court of appeals reversed. Pet. App. 1a-10a. It ruled that the labeling regulation did not improperly interfere with the practice of veterinary medicine. *Id.* at 5a-8a. Although the FDCA contemplated that States would continue to determine whether a medical practitioner "had selected wisely from among methods of treatment," "[n]othing in the history or structure of the Act permits drugs deemed ineffective or dangerous by the FDA to be

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received FDA approval. Congress has since deleted 21 U.S.C. 321(w)(3) from the FDCA, however, see the Generic Animal Drug and Patent Term Restoration Act, § 107(a)(1), Pub. L. No. 100-670 (Nov. 16, 1988), and this allegation is not in issue.

available for use." *Ibid.* (citing *United States* v. *Rutherford,* 442 U.S. 544 (1979)). That distinction was sensible, the court explained, because "no individual veterinarian will possess complete knowledge of the efficacy of a novel drug compound—let alone of its persistence in the food chain." *Id.* at 6a. The court also rejected petitioner's claim that, because veterinarians are exempt from the registration and inspection provisions of the FDCA when they compound medicines, the FDA's labeling regulation unlawfully intrudes into their medical practice. That argument, the court explained, rests on the erroneous assumption that a veterinarian is entitled to obtain any drug, even one not approved by the FDA. The limited exemption of practitioners from certain provisions of the FDCA does not entitle a veterinarian to obtain and use adulterated or mislabeled drugs. *Id.* at 7a.[7]

ARGUMENT

Petitioner claims that FDA's labeling regulation improperly interferes with the practice of veterinary medicine by depriving veterinarians of drugs they believe necessary to treat diseases in animals. The court of appeals correctly rejected that claim. The FDA's labeling regulation is consistent with the text and structure of the FDCA, and it serves the Act's public health goals by channeling bulk

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[7] The district court also found that the regulation was unreasonable because it placed on the distributor of bulk drugs what the court believed was an "impossible" burden of proving that bulk drugs will be used in a lawful manner by its customers. Pet. App. 21a-22a. The court of appeals rejected that conclusion, since a drug supplier can simply ask the recipient whether it possesses an approved NADA and can also examine the list of approvals published in the Federal Register. See page 3 note 2, *supra.* Petitioner has not renewed in this Court its claim that it is impossible to comply with the regulation.

animal drugs to uses in finished drugs that have been demonstrated to be safe and effective. Petitioner's interpretation of the FDCA, by contrast, would permit a drug manufacturer to market all drugs, including prescription drugs, outside the Act's elaborate approval mechanism. That result would turn on its head the system adopted by Congress to protect the public against the effect of unapproved new animal drugs on the food supply, and to protect the animals themselves. Accordingly, because the decision below is correct and does not conflict with any decision of this Court or of any other court of appeals, review by this Court is not warranted.

1. Congress has authorized the FDA to promulgate regulations exempting drugs from the requirement that labeling bear "adequate directions for use" if the agency finds that the requirement is "not necessary for the protection of the public health." 21 U.S.C. 352(f). Since that provision is "an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation," the FDA's regulation cannot be set aside unless it is "arbitrary, capricious, or manifestly contrary to the statute." *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 843-844 (1984) (footnote omitted). The agency's labeling regulation easily passes that test.

a. The FDCA establishes a comprehensive mechanism regulating the distribution of animal drugs to ensure that finished new animal drug products not demonstrated to be safe and effective will not be administered. Thus, a new animal drug cannot be marketed unless it is approved by the FDA, and to obtain the FDA's approval a drug manufacturer must prove, on the basis of adequate and well-controlled studies by qualified experts, that the drug is safe and effective for all uses recommended or suggested in the labeling, and that it will not cause harmful residues in meat, milk, or eggs. Pages 1-3, *supra*.

The FDA's labeling regulation plays an integral role in that process. It ensures that distributors like petitioner cannot circumvent the approval requirement by distributing bulk drugs to third parties who will thereafter create unapproved new drug products. See *DeFreese* v. *United States,* 270 F.2d 730, 736 (5th Cir. 1959), cert. denied, 362 U.S. 944 (1960) (bulk prescription drugs are not exempt from the labeling requirements of 21 U.S.C. 353(b) if the FDA has not exempted them). Cf. *United States* v. *Rutherford,* 442 U.S. at 551-559. Moreover, nothing in the legislative history of the Act suggests that a drug manufacturer or distributor may distribute misbranded or adulterated bulk drugs, or drugs that are deemed dangerous or ineffective by the FDA, simply because the recipient is a veterinarian.

b. Petitioner argues (Pet. 12-15) that Congress has implicitly exempted veterinarians (and therefore those who manufacture and distribute drugs destined for them) from the premarketing approval requirement, because Congress has exempted veterinarians and other medical practitioners from the registration and inspection provisions of the FDCA. 21 U.S.C. 360(g)(2), 374(a)(1)(B). As the court of appeals explained (Pet. App. 7a-8a), however, those limited exemptions have no application here. Veterinarians may use and compound, without registration, only those drug ingredients they may lawfully acquire, and they may not lawfully acquire misbranded bulk animal drugs. The registration and inspection exemptions do not justify the distribution and compounding of drugs when doing so violates other provisions of the FDCA. In fact, one of the reasons why Congress allowed practitioners to compound finished drug products is that the FDCA forbids drug manufacturers and distributors from marketing adulterated or misbranded components of finished drug products. The interpretation of the Act adopted by the court of

appeals therefore gives effect to both those limited exemptions and the premarketing approval provisions of the FDCA.[8]

There is no justification for creating an implicit exception to the requirements of the FDCA for the distribution of bulk animal drugs to veterinarians. Contrary to the assertions of petitioner and amici, the fact that veterinarians exercise professional judgment in treating animals is not a sufficient basis for inferring that Congress has exempted them from the limitations otherwise applicable to the distribution of new animal drugs. In fact, in 1962, when it added the efficacy requirement to the premarketing approval process, Congress concluded that the determination whether a drug is effective cannot rest on the knowledge and experience of individual physicians. As this Court noted in *Hynson,* "[t]he hearings underlying that 1962 Act show a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous." 412 U.S. at 619 (footnote omitted). See also *Warner-Lambert Co.,* 787 F.2d at 156 (in the 1962 amendments Congress rejected the notion "that individual physicians should be left to decide whether particular drugs were effective"). Instead of leaving to the judgment of individual practitioners what new drugs may be distributed, Congress has established an elaborate approval process for new human and animal drugs and prohibited the distribution of such drugs unless they have been proved safe and effective. Drug manufacturers and distributors are

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[8] As the court below stated (Pet. App. 9a): "The effect of § 352(f) and § 201.122 is that ingredients that can be used to produce 'new' drugs may be sold only to firms that hold approved (or have filed) new animal drug applications. The FDA carefully scrutinizes the activities of these manufacturers. This is a sensible result in light of the structure of the statute."

not exempt from that process when they distribute new animal drugs to veterinarians.

There is also no merit to petitioner's argument (Pet. 10-11) that restricting the drugs veterinarians can receive improperly interferes with the practice of veterinary medicine. As the court of appeals explained (Pet. App. 5a), the FDA may legitimately restrict the sale of drugs to or by practitioners pursuant to its statutory authority to prohibit the distribution of new human or animal drugs that have not been proved to be safe and effective. For example, in *United States* v. *Rutherford, supra,* this Court held that the FDCA does not permit physicians to obtain laetrile for use in terminally ill cancer patients without the FDA's prior approval of that drug.[9] See also *United States* v. *Evers,* 643 F.2d 1043, 1048 (5th Cir. 1981) (stating that the FDCA was plainly intended to control the availability of drugs for prescription or use by practitioners); *United States* v. *Articles of Drug,* 625 F.2d 665, 675 (5th Cir. 1980); *Rutherford* v. *American Medical Ass'n,* 379 F.2d 641, 643 (7th Cir. 1967), cert. denied, 389 U.S. 1043 (1968) (rejecting a request by a physician and his patients for an injunction against the FDA and others from interfering with the distribution of an unapproved cancer-treatment drug); cf. *Pharmaceutical Mfrs. Ass'n* v. *FDA,* 484 F. Supp. 1179, 1188 (D. Del.), aff'd, 634 F.2d 106 (3d Cir. 1980) ("The fact that the practice of medicine is an area traditionally regulated by the states does not invalidate those provisions of the Act which may at times impinge on some aspect of a doctor's practice."). For years the FDA,

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[9] Although the Court did not discuss whether the laetrile was in finished or bulk form, the difference is inconsequential. As the *Rutherford* Court stated with respect to other unapproved remedies for terminal patients, if the ruling had been limited to finished drugs, the market for bulk laetrile would not long have been overlooked by inventive minds. See 442 U.S. at 557-558.

under statutory authority, has required prescription drugs to be subject to the new drug approval process,[10] and virtually all major prescription drugs used or prescribed by practitioners have been approved by FDA. See, *e.g.*, 47 Fed. Reg. 46625 (1982). If petitioner were correct, the FDA's approval system for both human and animal drugs would be an unlawful infringement on the practice of medicine. No case supports such a proposition, and the authority is to the contrary. See *United States* v. *Ellis Research Laboratories, Inc.*, 300 F.2d 550, 552-553 (7th Cir.), cert. denied, 370 U.S. 918 (1962) (holding that licensed practitioners are not per se exempt from the adequate directions for use provisions of the FDCA).

The agency's construction of the FDCA is fully consistent with its underlying purpose of protecting the public health. See *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784, 798 (1969). The unrestricted distribution of bulk drugs would expose the public to the risk of harmful residues in food, since none of the finished

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[10] When Congress required the approval of new drugs and new animal drugs under 21 U.S.C. 355 and 360b, it contemplated that the FDA would have authority to approve prescription as well as over-the-counter drugs. For example, 21 U.S.C. 353(b), which establishes the criteria for the dispensing of human drugs, explicitly refers to prescription drugs that must otherwise be labeled as required by 21 U.S.C. 352(f). See 21 C.F.R. 201.105(c)(2); *United States* v. *Colahan*, 635 F.2d 564 (6th Cir. 1980), cert. denied, 454 U.S. 831 (1981). Congress has recently codified the requirements for veterinary prescription drugs. See the Generic Animal Drug and Patent Term Restoration Act, § 105, Pub. L. 100-670. The FDA has approved a large number of animal drugs that are so restricted, as shown in the approval regulations that are published in 21 C.F.R. Pt. 520 *et seq.* The drugs are approved in finished form and are subject to detailed labeling and other requirements, including labeled directions and conditions for use. 21 C.F.R. 201.105. Section 201.100 has similar labeling requirements for human prescription drugs.

animal drug products compounded by veterinarians will have been subjected to the stringent testing requirements set forth in the Act to determine what (if any) residues occur in edible food products. For example, during the approval process for a new animal drug that is to be used in food animals, the FDA establishes the withdrawal time[11] based on studies done with the finished drug product that will be marketed if the FDA approves the NADA. An approved drug product is formulated and manufactured in a particular way; it contains specified inactive ingredients, as well as an active ingredient obtained from a particular source; and it is manufactured under specified conditions. See, *e.g.*, 21 C.F.R. 514.1 (b)(4)-(7). Differences in any of those factors, especially in the choice of inactive ingredients, can significantly affect the amount and kind of drug residue that occurs in the food the public consumes.[12] It is for such reasons that the FDCA requires that each individual drug product be tested to determine whether it is safe as well as effective in its finished form.

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[11] The withdrawal time is the length of time prior to slaughter (or marketing of milk or eggs) for which use of the drug is to be discontinued in order to ensure that no harmful residue will occur in edible products.

[12] See 21 C.F.R. 514.1(b)(4)-(8); 50 Fed. Reg. 27016 (1985); *Generix*, 460 U.S. at 455-456; *United States* v. *Undetermined Quantities of Various Articles of Drugs* * * * *Equidantin Nitrofurantoin Suspension*, 675 F.2d 994, 1001 (8th Cir. 1982), cert. denied, 460 U.S. 1051 (1983); *United States* v. *Premo Pharmaceutical Laboratories, Inc.*, 511 F. Supp. 958, 963-965 (D.N.J. 1981). These cases explain how differences in a drug's actions can be caused by differences in ingredients and formulations. The tragedies that can result from the use of drugs that are similar to approved drugs, but are not themselves approved, and from the use of seemingly innocuous but unapproved inactive ingredients, are explained in *Pharmadyne Laboratories, Inc.* v. *Kennedy*, 466 F. Supp. 100, 105-106 (D.N.J.), aff'd, 596 F.2d 568 (3d Cir. 1979), and *Equidantin*, 675 F.2d at 998.

Petitioner's interpretation of the statutory scheme, by contrast, would expose the public to serious health risks. Under the procedure advocated by petitioner, each veterinarian would be free to use any inactive ingredient he chooses, to compound any drug in any manner he wishes, and to establish his own withdrawal times, if any. As the court of appeals recognized, "no individual veterinarian will possess complete knowledge of the efficacy of a novel drug compound—let alone of its persistence in the food chain." Pet. App. 6a. This case illustrates the nature of those risks. Several of the drugs that are the subject of this action fall into categories found to cause cancer in test animals. *Ibid.* Those drugs, accordingly, present a risk of cancer to humans if residues are found in food.[13]

Petitioner asserts (Pet. 6-7) that veterinarians need bulk drugs to treat otherwise untreated diseases. That is a policy question for Congress and the FDA to decide. Moreover, petitioner's claim is undercut by its admission (Pet. 2) that many of the drugs seized in this case are "common, well-known products," thus suggesting that the motivation for the use of many bulk drugs may be economic, not therapeutic.

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[13] The FDA has withdrawn existing approvals for finished drugs that contain dimetridazole, 52 Fed. Reg. 25312 (1987), and has proposed to withdraw approvals for finished nitrofuran products (including nitrofurazone) because of the risk of residue in food. 49 Fed. Reg. 34965 (1984). Further, one of the sulfonamides (sulfas) has recently been found to cause cancer in test animals, 53 Fed. Reg. 15886 (1988), and illegal residues of sulfas have been found on a continuing basis in swine. See 50 Fed. Reg. 20796 (1985). See also 21 C.F.R. 510.450(a)(1) (concerning residues of sulfas).

The FDA has also found that drugs in another category among those that were the subject of this action—antibiotics—are new animal drugs, since those drugs are particularly capable of causing injurious drug residues in meat, milk, and eggs. See 21 C.F.R. 510.110; *Rhone-Poulenc*, 636 F.2d at 750 (an example of the harmful residue that can occur in human food as a result of animal drug use).

Finally, petitioner argues (Pet. 16-18) that the decision below is inconsistent with the Virus-Serum-Toxin Act (VSTA), 21 U.S.C. (& Supp. IV) 151-159. Petitioner did not raise that claim below, but it lacks merit in any event. The VSTA is an entirely separate law and supplies no assistance in interpreting the provisions of the FDCA. If anything, that Act supports the court of appeals' decision. The VSTA exempts biologics prepared by veterinarians from the Act's premarketing approval requirements by exempting such products from the licensing provisions that apply to other biologics. 21 U.S.C. (Supp. IV) 154a. That provision shows that Congress knows how to exempt veterinarians from premarketing approval requirements when it wishes to do so, and it has not done so in the case of bulk animal drugs.

c. The FDA's construction of the FDCA is entitled to deference. The labeling regulation was adopted in 1952, and the agency has for many years construed the Act to prohibit the distribution of a bulk drug that is used to create an unapproved new animal drug. See FDA *Compliance Policy Guide* § 7125.10 (July 13, 1976), *quoted at* Pet. App. 7a ("[V]eterinarians may use in the compounding of prescriptions for their private practice whatever bulk drugs or other pharmaceuticals *they may lawfully purchase*.") (emphasis added).[14] Neither the labeling regulation nor any other in the intervening years has made

[14] Since 1952, the FDA's bulk drug exempting regulation has contained a condition that the finished drug product not be an unapproved "new drug." 21 C.F.R. 1.106(l) (promulgated July 25, 1952, 17 Fed. Reg. 6818). The FDA has regulated bulk drugs for many years (see, *e.g.*, *Arner Co.* v. *United States*, 142 F.2d 730, 734-736 (1st Cir.), cert. denied, 323 U.S. 730 (1944)), including bulk drugs intended for use by veterinarians. See, *e.g.*, *United States* v. *Articles of Drug* * * * *17 1200-Gram Drugs* * * * *Sulfachlorpyridazine*, Civ. No. F74155 (E.D. Cal. Feb. 9, 1977); FDA *Compliance Policy Guide* § 7125.10, which has been in effect at least since 1976.

an exception for drugs sold to practitioners. Moreover, deference is particularly appropriate here, since the Act delegates authority to the FDA to protect the public health, and the FDA's judgment whether labeling is necessary for that purpose is "within its area of special expertise, at the frontiers of science." *Baltimore Gas & Elec. Co.* v. *NRDC*, 462 U.S. 87, 103 (1983). See also *Young* v. *Community Nutrition Inst.*, 476 U.S. 974, 981 (1986).

In sum, petitioner's construction of the Act not only would risk contamination of the food supply but also would undermine the FDA's entire system for regulating bulk drugs, regardless of whether the drugs are intended for use in the manufacture of human or veterinary drugs, or whether the finished products are intended for prescription or over-the-counter use. Section 201.122 applies in each circumstance. The FDA has properly exercised its authority to regulate bulk drugs early in the distribution chain in order to minimize the risk that consumers will be exposed to adulterated and misbranded finished drug products.

2. There is no conflict among the circuits on the question presented by this case. No other court of appeals has considered whether the labeling exemption in 21 C.F.R. 201.122 is within the FDA's statutory authority, and only one other district court has considered that issue. *United States* v. *Algon Chemical Inc.*, 689 F. Supp. 394 (D.N.J. 1988), appeal pending, No. 88-5478 (3d Cir. Jan. 9, 1989), *reprinted at* Pet. App. 34a-44a. The district court in that case relied on the district court's decision in this case (Pet. App. 41a-43a), which was reversed by the court of appeals. A conflict between a court of appeals and a district court, however, does not warrant review by this Court.

There is no conflict between the other decisions cited by petitioner (Pet. 19-22) and the court of appeals' decision in

this case. For example, petitioner errs in relying on excerpts from *Chaney* v. *Heckler*, 718 F.2d 1174, 1179-1182 (D.C. Cir. 1983), rev'd on other grounds, 470 U.S. 821 (1985). That case involved the use by physicians of drugs that had been *approved* by the FDA for certain uses but not for the specific use—the administration of lethal injections to condemned prisoners. By contrast, this case involves the use of *unapproved* drugs. Moreover, the court of appeals held in that case that the FDA had the authority to limit the uses that a physician could make of an approved drug. 718 F.2d at 1179-1182. *United States* v. *Evers*, 643 F.2d 1043 (5th Cir. 1981), also relied on by petitioner, held that a physician did not violate 21 U.S.C. 352(f) and 21 C.F.R. 201.5 by distributing a drug to his patients. But the case is not on point because the court there expressly held that, since the drug was a prescription drug prescribed and dispensed by a licensed physician, it was exempted from 21 U.S.C. 352(f)(1) under provisions not relevant here. 643 F.2d at 1051, 1053. Finally, *Pharmaceutical Mfrs. Ass'n* v. *FDA*, *supra*, actually supports the judgment below: it upheld an FDA regulation, promulgated in part to enforce the labeling provisions of 21 U.S.C. 352(a) and (f), that required physicians and pharmacists to supply patients with certain information when drugs containing estrogen were prescribed for them. The court expressly rejected the claim that the regulation interfered with the practice of medicine. 484 F. Supp. at 1184-1185.[15]

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[15] *Grinspoon* v. *DEA*, 828 F.2d 881 (1st Cir. 1987), cited by petitioner (Pet. 21-22), is not remotely relevant. The question there involved the meaning of a statutory requirement for classifying a substance as a Schedule I narcotic under the Controlled Substances Act, 21 U.S.C. 811-812. The court held that the fact that the FDA has not approved a substance does not automatically render it a controlled substance, since the FDA may not approve a substance for reasons having nothing to do with its medical use. 828 F.2d at 887.

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

CHARLES FRIED
Solicitor General
JOHN R. BOLTON
Assistant Attorney General
ROBERT S. GREENSPAN
LAWRENCE G. MCDADE
Attorneys

THOMAS SCARLETT
Chief Counsel
RICHARD E. GEYER
Attorney
Food and Drug Administration

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Supreme Court of the United States

OCTOBER TERM, 1988

9/1 KG CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, AND SCHUYLER LABORATORIES, INC.,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

BRIEF OF THE HUMANE SOCIETY OF THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

MURDAUGH STUART MADDEN
(*Counsel of Record*)
ROGER A. KINDLER
2100 L Street, N.W.
Washington, D.C. 20037
(202)833-3360

Counsel for Amicus Curiae

PRESS OF BYRON S. ADAMS, WASHINGTON, D.C. (202) 347-8203

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CONSENT

The Humane Society of the United States has obtained written consent to file a brief as amicus curiae from Petitioner and Respondent, pursuant to Sup. Ct. R. 36.1.

INTEREST OF AMICUS CURIAE

The Humane Society of the United States ("HSUS") is a non-profit, charitable corporation, organized under the laws of the State of Delaware, with principal offices at 2100 L Street, N.W., Washington, D.C. and regional offices throughout the United States. It has an active membership of over 252,000 persons residing in every state of the United States and in the District of Columbia, and a mailing constituency of over 579,000 persons nationwide, who share a commitment to the prevention of cruelty to animals and to the promotion of all aspects of animal welfare. In the past thirty years, the HSUS has devoted considerable resources to researching and publicizing many aspects of farm and companion animal welfare. The HSUS publishes informative and educational materials relating to the humane treatment of farm and companion animals and, upon request, consults with and advises Congress as well as agencies of federal, state, and local government.

The Humane Society of the United States has a long-standing interest in the relationship between veterinarians and the animals which they treat, as well as the ethical aspects of that relationship. Apart from the interests of the Petitioner, the health and welfare of animals and of society will be strongly affected by the final disposition of this case. It is the duty of the HSUS to protect the interests of those animals which

can not, of course, protect themselves. Therefore, the outcome of this case is inextricably linked to the most fundamental charitable purposes of the HSUS.

The HSUS believes that in order to assure the humane treatment of animals and to promote the public welfare, veterinarians must have access to those bulk chemicals from which they compound a large number of the drugs used in the daily practice of veterinary medicine for the alleviation of disease and suffering in animals and therefore disagrees with the decision reached by the Seventh Circuit Court of Appeals.

SUMMARY OF ARGUMENT

The health and well-being of many numbers and species of animals will be jeopardized if the current ability of the veterinarian to prepare drugs is restricted. There exist many common diseases and conditions for which there are no FDA-approved drugs. This situation is not likely to change, because it is not cost-effective or feasible for many pharmaceutical manufacturers to test and see through to approval a significant number of commonly used and beneficial drugs for a large number of animal species. Restrictions on the use of such drugs will contribute to the needless suffering of many animals from disease and injury. In addition, specialties and research in the animal health field will be set back for many years.

The wide variety of animal species and the multitude of illnesses which may befall these animals make it necessary for the veterinarian to frequently prescribe newer, more powerful, yet not specifically labelled antibiotics and combinations thereof, in order to minimize drug residue problems while maximizing therapeutic effectiveness. Due to their highly spec-

ialized and rigorous professional training, veterinarians are uniquely qualified to make such decisions on a day-to-day basis. If the decision of the Seventh Circuit Court of Appeals is allowed to stand, there will be grave implications for the veterinary profession and its ability to treat animals effectively. Due to the requirement of approval, it is likely that a veterinarian could be held liable if an animal were to die after being treated with an unapproved drug, yet in many cases such treatment may be necessary in order to alleviate an animal's suffering or to save its life. The fear of being sued will thus produce the deleterious effect of causing suffering and loss of animals that might otherwise have been prevented. Other aspects of public policy also support reversal of the decision reached by the Seventh Circuit Court of Appeals. In order to prevent the entry of diseased animals into the stream of commerce, it is necessary for veterinarians to be able to prescribe and administer drugs as is deemed necessary. Factory farming leads to diminished resistance to disease and to increases in the number of injuries sustained by food animals, ever requiring the veterinarian to prescribe new drugs and combinations thereof.

There are also obvious anti-competitive aspects to the outcome of this case. The requirement of FDA approval will cause smaller pharmaceutical companies to abandon their animal drug business, leading to a critical narrowing of the veterinary pharmacopeia. There will be no appropriate drugs for some species or diseases, which will cause unnecessary suffering and death to animals and will threaten the public welfare. For all of these reasons, the decision reached

by the Seventh Circuit Court of Appeals is clearly against the larger interests of society.

ARGUMENT

I. CURRENT VETERINARY PRACTICES ARE NECESSARY TO ALLEVIATE ANIMAL SUFFERING AND PREVENT UNNECESSARY DEATHS

As argued below in Part II, the veterinarian has a moral and ethical responsibility to protect the animal's interests, and the animal should thus receive the best possible veterinary treatment to alleviate suffering and illness. A limitation on the ability of the veterinary profession to practice as it thinks best will contribute to the suffering of countless animals due to loss of the veterinarian's power to prescribe many extremely beneficial drugs and treatments. In taking its current position, the FDA places the welfare of animals in jeopardy, by violating the animal's interest in receiving the best and most appropriate veterinary treatment that the client is willing and able to pay for.

There are a number of commonly encountered diseases afflicting both food and companion animals which cannot be treated with currently approved drugs, but which are regularly treated with unapproved drugs. In beef or dairy cattle, there are a number of regularly occurring health problems for which there simply is no FDA-approved drug which is effective. For example, there are no approved tranquilizers which can be used to restrain beef cattle which are in labor and need to be restrained. Thus, the use of Rompun, which is only approved for use in horses, may be necessary. *Verified Statement of J.J. Crouch, D.V.M.* (April 15, 1987) at 2-3, *submitted*

in, Cowdin v. Young, Case No. 87-0912F_(W.D.La. 1987).

In the treatment of acute coliform mastitis, an inflamation of the mammary gland due to infection, the determination of the amount and type of drugs used must be calculated "in proportion to the animal's reaction to the endotoxin being produced by the bacteremia, and the approved labels for drugs to treat this condition simply can not take this factor into account;" Gentamicin and Banamine are often the most effective drugs but are approved only for horses. *Id.,* at 3; *Verified Statement of Mark F. Hemmerich, D.V.M.* (April 15, 1987) at 2, *submitted in, Cowdin v. Young, supra.* Another highly prevalent condition is respiratory infection due to *Pasteurella haemolytica* and *Pasteurella multocida.* This condition can spread rapidly in winter if there is high humidity and fairly mild weather because the cattle are kept close together in barns. If only approved medications were used for treatment, as many as 75% to 80% of those afflicted would die. *Verified Statement of Douglas M. VanDamme, D.V.M.* (April 15, 1987) at 2, *submitted in, Cowdin v, Young, supra.*

In swine, coccidiosis is a common condition. This disease may cause neonatal scours in pigs that can kill up to 50% of the baby pigs in a farrowing; it can only be effectively treated with unapproved bovine coccidiostats in the swine ration or administered orally to the baby pigs. Without these drugs, 10% to 15% of a swine herd may be lost. *Verified Statement of Michael B. Davis, D.V.M.* (April 27, 1987) at 1, *submitted in, Cowdin v. Young, supra.* There are no approved treatments for colibacillosis (baby pig diarrhea) despite the fact that this disease occurs on most

hog-producing farms and that rapid antibiotic resistance is common. *Verified Statement of Wiley R. McVicker, D.V.M.*, (April 28, 1987) at 2, *submitted in, Cowdin v. Young, supra.*

In goats, the FDA has only approved wormers such as Atrobine and Neomycin; for approximately 90% of the conditions and disorders in goats there are no approved drugs. *Verified Statement of Robert M. Clack, D.V.M.* (April 28, 1987) at 3, *submitted in, Cowdin v. Young, supra.* There are no approved anesthetics available for goats. *Statement of Wiley R. McVicker, D.V.M.* (April 28, 1987) at 2, *submitted in, Cowdin v. Young, supra.* There are no approved drugs to treat *any* known diseases in buffalo. *Id.*, at 3. The well-documented lack of effective approved anesthetics for use in any animals (five of the veterinarians who submitted verified statements in *Cowdin v. Young* stated that there are no effective approved anesthetics for any animals) means that an unconscionable situation will exist if the FDA adheres to its new policy—animals will be subjected to surgery without anesthesia or will suffer and die.

Veterinarians find it necessary to use even those drugs which are FDA-approved in a manner other than that in which they are approved. For example, the approved label dosage for procaine penicillin aqueous injection is 3,000 units per pound of body weight, but for various disease conditions the effective dosage may be 20,000 to 60,000 units per pound. *Verified Statement of Daniel J. Lohnes, D.V.M* (April 28, 1987) at 1, *submitted in Cowdin v. Young, supra.* The approved dosage of oxytetracycline hydrochloride injection is far too low to effectively treat shipping fever pneumonia in cattle. *Id.*, at 1-2. Bacteria con-

tinue to develop resistance to antibiotics, while the FDA-approved dosages remain static, precluding effective treatment.

Several drugs approved for use in humans but not in animals are necessary to treat commonly encountered illnesses in companion animals. Tapazole, a human medicine for hyperthyroidism, is used on the increasing number of cats which suffer from this condition. Tussigon is a human medicine used on dogs with a common cough. Hydroxyzine hydrochlorate, an antihistamine for humans, is also used to treat dogs with severe pruritis (itching); without this treatment, many dogs would scratch themselves until they bleed. *Statement of Carvel G. Tiekert, D.V.M., President of the American Veterinary Holistic Medical Association* (December 1, 1988). Despite the common incidence of diabetes in companion animals, no form of insulin is approved for use in animals.

It is simply not cost-effective or feasible for small pharmaceutical manufacturers to test and see through to approval a significant number of commonly used and beneficial veterinary pharmaceuticals for a large number of animal species. Thus, this new FDA approach to the use of bulk drugs will not only place millions of farm and companion animals, such as cattle, horses, cats, and dogs, outside the domain of competent and appropriate treatment, it will also place at risk many species of wildlife needing veterinary treatment. Pet rabbits and gerbils, parakeets and parrots, iguanas and ferrets, zoo- and ranch-raised wildlife of all kinds, buffalo and antelope, foxes and chinchillas will also be placed in jeopardy, unless the veterinarian is able to exercise his or her discretion

over the use of pharmaceuticals not yet approved for use.

Recently emerging veterinary specialties, such as oncology, opthalmology and cardiology which rely heavily upon the use of drugs only approved by the FDA for human use will be set back many years. The astronomical financial burden imposed by the FDA's requiring approval of the use of all drugs on all species will render it difficult for any new areas of animal medical care to be explored. (Due to the new policy of heavy-handed intervention on the part of the FDA, it will be difficult enough for veterinarians to use those techniques and drugs that have been proven over time.)

By making the use of many extremely beneficial drugs suddenly off limits, the FDA will contribute to the needless suffering of farm animals from disease and injury. Animals will be untreated or left to die, or necessary surgery will be performed without anesthesia. The policy being pursued by the FDA will gravely and unnecessarily endanger the lives of millions of animals and may endanger the very existence of many species. The FDA's goals would be better served if the FDA would take measures to restrict lay use of animal drugs by farmers who lack professional training and are more concerned with profits than with their animals or the public health.

II. THE ROLE OF VETERINARIANS IN OUR SOCIETY REQUIRES THEIR BEING ABLE TO TREAT ANIMALS WITH MIXTURES OF BULK CHEMICALS IN ACCORDANCE WITH LONG-STANDING PRACTICE

Before the significance and consequences of the ruling of the Seventh Circuit Court of Appeals can be

adequately and objectively reconsidered, the role of the veterinarian in society, and in animal agriculture in particular, must be taken into account. The practitioner of the veterinary sciences has very strong ethical and professional obligations both to society and to the animals which he or she treats.

The role of the veterinarian is multi-faceted and complex, as reflected in the *Veterinarian's Oath* where the animal doctor pledges to use his or her skills:

> . . . for the benefit of society through the protection of animal health, the relief of animal suffering, the conservation of livestock resources, the promotion of public health, and the advancement of medical knowledge.
>
> I will practice my profession conscientiously, with dignity, and in keeping with the principles of veterinary medical ethics.

N.E.Hutton, "Animal Welfare: An AVMA Perspective," *California Veterinarian*, Jan. 1983, at 31.

From the perspective of veterinary ethics, this means that veterinarians must recognize their responsibilities to their clients, to society generally, and to their animal patients. Occasionally, the demands the client or of society may conflict with the best interests of the animal patient, but the veterinarian nonetheless has a moral obligation and an ethical responsibility to protect the animal's basic interest in humane consideration and to be the recipient of the best possible treatment for the alleviation of suffering and sickness. *See*, M.W. Fox, "Veterinarians and Animal Rights," *California Veterinarian*, Jan. 1983, at 15. The American Veterinary Medical Association

(AVMA) has recognized the obligation of the veterinarian not only to society, but to animals as well. In 1981, the AVMA Animal Welfare Committee adopted as a guiding principle that "AVMA has a long-term concern and commitment to the welfare and humane treatment and care of animals." See, N.E. Hutton, *supra*, at 31. The balance between serving the best interests of the public/client and the animal/patient is clearly a delicate one that entails both subjective and objective judgment by the veterinarian.

Due to the wide variety of animal species and the multitude of illnesses which may afflict these species, veterinarians must frequently prescribe newer, more powerful, yet not specifically labelled antibiotics and combinations thereof, to minimize drug residue problems while maximizing therapeutic effectiveness. Veterinarians are uniquely qualified to make such decisions on a day-to-day basis. Veterinarians must undergo a great deal of educational preparation to practice. All states require licensing, and to become licensed a veterinarian "must have a degree from an accredited college of veterinary medicine, and pass a thorough examination given by a state's board of examiners." *Animal Health Technology* 451 (E.J. Catcott 2d ed. 1977). To earn the degree of Doctor of Veterinary Medicine (D.V.M.), the veterinarian must complete a minimum of two years pre-veterinary college study, followed by four years of professional education. Professional journals, consultation with collegues, continuing education and post-graduate education also keep the veterinarian informed as to developments in the field. *Id.*, at 452-453.

"As the veterinarian because of his specific training and experience should be the major interpreter of the

relevance of animal disease to the human population, he must play an important part in the formulation of disease control policies which have a public health purpose." Brander, "The Relevance of Human and Animal Health Considerations in Veterinary Education," *Veterinary Epidemiology and Economics* 325 (1980). The veterinarian is the key figure in the assurance of drug safety. The pharmaceutical company may manufacture a safe product, and one which has been approved by the FDA, but if the veterinarian does not use the drug properly in treating his or her patients then no amount of FDA approval will assure animal or public health. It is thus clear that the FDA policy is not only obstrusive and heavy-handed, but is ill-suited to achieve its goals.

If the FDA prevails in its attempts to require FDA approval of the drugs involved in this case and to control the manner in which veterinarians compound medicines for use in the course of their professional practices, the result will be disastrous for the veterinary profession. A veterinarian could be held liable if an animal were to die after being treated with an unapproved drug or one that was not specifically labelled for use on that animal's species. However, in many cases, such treatment may be necessary to alleviate the animal's suffering, or to save its life. The fear of being sued will produce the deleterious effect of causing suffering and loss of animals that would have otherwise been spared. Restrictions on the ability of veterinarians to practice as they deem necessary will only hurt the animal population and society as a whole. Unless the veterinarian is allowed to exercise his or her discretion over the use of pharmaceuticals not yet approved for use, society and the

veterinarian's animal patients will suffer and the veterinarian will not be able to live up to the standards imposed by his or her sacred oath.

III. PUBLIC POLICY MILITATES AGAINST THE REQUIREMENT OF FDA APPROVAL OF EVERY DRUG USED IN THE PRACTICE OF VETERINARY MEDICINE

The Amicus Curiae recognizes and supports the FDA's interest in protecting the public health and welfare. However, the policy apparently adopted by the FDA to deal with those health hazards, illustrated by FDA actions which precipitated this case, is ill-suited to achieve these goals. In order to prevent the entry of diseased food animals into the stream of commerce, it is crucial for veterinarians to be permitted to prescribe antibiotics as they deem necessary. "It is . . . a responsibility of the veterinarian to be a source of knowledge on the animal diseases which could cause an epidemic of disease in human beings." Brander, *supra*, at 321. "There are approximately 250 diseases which are considered zoonotic, i.e. can spread from animal to man, although many of them are not readily transmitted to man because they predominate in wild animals or in small rodents, there are a significant number which are always potentially transmissable and which can be controlled by preventative methods . . . both the effective use of drugs, vaccines and disinfectants, and . . . also on a mutual understanding of both epidemiology and the relevance of therapy." *Id.*, at 324.

The widespread use of "factory farming"—practices involving the raising of food animals in massed, crowded conditions designed to maximize economies of scale—has resulted in impaired immunity and

unique health hazards in food animals. Factory farm animal experts have observed that animals in the factory farm setting become "stressed," and react to this stress by burning up "energy and nutrients that would otherwise go toward growth, gestation, lactation, and disease resistance . . . When an animal is stressed, its defenses are down and it is more prone to infectious diseases . . . the stressed animal may catch a disease which spreads to the second animal." J. Mason & P. Singer, *Animal Factories* 21-23 (1980). The crowded conditions of the factory farm setting increase the likelihood and frequency of fighting, which also causes injury. *Id.*, at 23. Pig and dairy factories are susceptible to diseases aggravated by the factory farming conditions. *Id.*, at 25. Calves raised for veal suffer from the effects of deliberately-induced anemia, which results in decreased resistance to disease. *Id.*, at 27. *See also, generally*, Brander, *supra*, at 319-324.

Because of this, it is increasingly necessary for veterinarians to prescribe newer, more powerful antibiotics and combinations thereof, although many of these have not been specifically labelled for use on the particular species being treated.* While the FDA

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* One British veterinarian has observed the necessity of regularly introducing new antibiotics to treat animal infections which might otherwise spread to humans as the animals are consumed by humans:

> If an animal is fed antibiotics the organisms in the gut may duly develop resistance to that antibiotic, or antibiotics. If, however, those antibiotics are no longer administered to the animal, the organisms in the gut continue to remain drug resistant. Should that animal acquire a salmonella infection the drug resistance of

approval process may be sufficient to cope with the testing and approval of drugs used on humans, a number of critical problems will be created by the requirement of testing and approval of a large number of drugs, to be used for treatment of an even larger variety of illnesses, and to be applied to a multitude of species.

Moreover, there are also obvious anti-competitive aspects to the requirement of FDA approval and labeling. It would not be cost-effective or economically feasible for smaller pharmaceutical companies to conduct tests on the various species in order to conform with FDA protocols prior to approval for use in specified animal species. This will lead to the demise of many small veterinary biologics companies and to a critical and tragic narrowing of the veterinary pharmacopeia. It will also inevitably lead to control over production of a limited spectrum of veterinary drugs by the small number of pharmaceutical companies which possess the almost unlimited resources necessary to conduct new product tests on various species for FDA-approved labeling.

An "orphan" drug problem, as in human medicine, is also then likely to arise where no appropriate med-

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> those organisms already present can be passed over to the new infecting salmonella. Should the salmonella acquired by the animal cause illness in that animal, the giving of antibiotics to which the organism has acquired its resistance will not only have no therapeutic effect whatsoever, but will probably make the animal's condition worse by destroying those organisms already in the bowel which may not have required antibiotic resistance.

D.J.H. Payne, "Medical Opinion on Antibiotics in Agriculture," *Factory Farming* 26 (1970).

ications are available on the market for some species and disease conditions because they are no longer being manufactured. These occurrences would threaten not only the welfare of companion and farm animals: advances in the fields of comparative medicine and therapeutics would also be slowed dramatically. This would have negative social consequences since many advances in human medicine are made from veterinary clinical studies on sick animals, most notably regarding cancer and immune-deficiency diseases. *See, Animal Health Technology, supra,* at 451. Therefore, the requirement of FDA approval of drugs such as those involved in this litigation is clearly against the larger interests of society.

CONCLUSION

The FDA should not be empowered to completely control the manner in which veterinarians may compound medicines for use in their veterinary practices. In order for veterinarians to serve society and their animal patients, the regulatory requirement that the drugs they commonly use bear specific directions for use must be interpreted so as to avoid the consequences described above. Any decision otherwise would senselessly limit the spectrum of drugs which veterinary practioners may use, and would make the FDA alone the sole authority over which drugs private veterinarians may give to their animal patients. The FDA would thus clearly be imposing on the ability of veterinarians to practice their healing art.

The harm that such a policy would cause to the many far outweighs any benefits that a restrictive regulatory policy would provide. Millions of animals will suffer and die, with attendant consequences to

the food supply. For all of these reasons, as well as those reasons set forth in the brief of Petitioner, Schuyler Laboratories, Inc., this Court should exercise its discretion to review the decision reached by the Seventh Circuit Court of Appeals.

Respectfully submitted,

MURDAUGH STUART MADDEN

ROGER A. KINDLER

2100 L Street, N.W.
Washington, D.C. 20037
(202) 833-3360

Counsel for Amicus Curiae
The Humane Society of
The United States

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DAVID A. OLDFIELD
LeFevre, Zeman, Oldfield & Schwarm
Law Group, Ltd.
303 S. Seventh Street
P.O. Box 399
Vandalia, IL 62471
618/283-3034

Attorney for AMERICAN FOOD ANIMAL VETERINARY MEDICAL ASSOCIATION

NO. 88-614

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DAVID A. OLDFIELD
LeFevre, Zeman, Oldfield & Schwarm
Law Group, Ltd.
303 S. Seventh Street
P.O. Box 399
Vandalia, IL 62471
618/283-3034

Attorney for AMERICAN FOOD ANIMAL VETERINARY MEDICAL ASSOCIATION

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IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1988

9/1 K G CONTAINERS, more or less, of an article of drug for Veterinary use, and,	)
SCHUYLER LABORATORIES, INC.,	)
Petitioners,	) No. 88-614
v.	)
UNITED STATES OF AMERICA,	)
Respondent.	)

BRIEF OF AMERICAN FOOD ANIMAL VETERINARY MEDICAL ASSOCIATION IN SUPPORT OF PETITIONERS' PETITION FOR WRIT OF CERTIORARI

The Supreme Court must grant a Writ of Certiorari in this case. It is imperative that the Writ of Certiorari be granted because there will be devestation in the food producing animal populations which will result in a sharp decline in the quality and availability of meat, milk, and eggs which will severly effect every American. The Seventh

Circuit's incorrect interpretation of the powers of the Food and Drug Administration (hereinafter referred to as "FDA") gives the FDA unprecedented control over the practice of veterinary medicine and will make it impossible for veterinarians to practice their healing arts in a legal, ethical manner. The potentially devestating consequences to our food supply of the Seventh Circuit's decision cannot be over emphasized and thus neither can the necessity for this Court's review of that decision. Written consent to file this Brief, Amicus Curiae, has been given by both parties.

I. INTRODUCTION

American Food Animal Veterinary Medical Association is an Illinois not for profit corporation whose members are veterinarians. The veterinarian profession will be directly affected by the decision in this case. For the food animal veterinarian the utmost con-

cern is a safe and abundant supply of meat, milk, and eggs. It is the veterinarian's education, training, and experience which make him the most qualified person to make decisions regarding the health of the animals in his care to make certain there is an abundant and safe supply of meat, milk, and eggs. In accordance with the law, veterinarians must have free access to those bulk chemicals from which they compound most of the drugs used in their daily decisions regarding food animals. This brief, while touching on various aspects of the law, will focus on the policy aspects of this case since it is one of first impression. The effects of the decision by the Seventh Circuit are so far reaching and so disasterous that this Court must grant the Writ of Certiorari.

II. ISSUE

Whether the Food & Drug Administration can of its own accord extend its authority so as to

control what veterinarians may prescribe for their patients in disregard of the expressed intent of the law?

III. FACTS

Certain chemicals were seized by the government from the Petitioner, Schuyler Laboratories, Inc. (hereinafter referred to as "Schuyler"). The government complained that these chemicals were misbranded under 21 U.S.C. §352(f)(1) because the packaging did not contain adequate directions for use. In addition the government complained that five (5) lots of the chemicals were adulterated as a matter of law because they were antibiotic drugs. Appendix of Appellant filed in the Seventh Circuit at 2.

For 16 years Schuyler has been in the business of providing pure bulk materials to veterinarians to use in their practice. The FDA has all along been familiar with the

business of Schuyler. There is no question regarding the purity of the chemicals nor is there any question that the chemicals were meant to be distributed in bulk to veterinarians to be used in their practice and not to laymen. Supplemental Appendix of Appellees filed in Seventh Circuit (hereinafter cited as "Aee") at 00017, 18, 19.

Finally, there is a total lack of evidence to imply that the chemicals in general are illegal; that residues were occurring in milk, meat, or eggs as the result of the use of these chemicals by veterinarians; or that there is a public health threat caused by the veterinarians' long-standing practice of compounding medications from bulk drugs.

IV. ARGUMENT

While the statutes and terms in the drug area are complicated, the ultimate issue in this case is quite simple. It is simply a ques-

tion whether the educated, licensed, and experienced professional veterinarian is in a better position to make judgments regarding the treatment of food animals or are such decisions to be made on a mass level by the bureaucrats of the central government. We are not questioning the FDA's authority to act against practices which will cause residues in the food supply or to otherwise protect public health. That is not the issue here and no where has the FDA contended that the health of the consuming public is the issue. It is simply whether the FDA can control indirectly what the veterinarian may prescribe in the course of his healing arts by controlling what chemicals are available to the veterinarian when the FDA cannot directly control what the veterinarian may prescribe.

A. The Seventh Circuit erroneously interpreted the Food, Drug, and Cosmetic Act and

blindly deferred to the misinterpretation of that Act by the FDA. The opinion below admits that the FDA is trying to do in this case what it has not done before in controlling the practice of veterinary medicine. The lower court acknowledges the damage which the FDA's interpretation of the Food, Drug & Cometic Act (hereinafter referred to as "Act") will do to food producing animals and the shackles which will be placed upon veterinarians. Although the briefs presented to the Seventh Circuit presented a rather extensive analysis of the history of the Act, the Seventh Circuit essentially ignored that history and instead provided a novel interpretation of that history so that the intention of the Act not to interfere with the practice of the healing arts is narrowed to the point where only medical licensure and discipline continue to be outside the province of the FDA. Not even the FDA has been

so bold as to assert this kind of authority yet that is the position put forth in the opinion by the Seventh Circuit. While deference is due an administrative body, blind grants of power by the courts should not be. A proper review of the Act clearly shows that the FDA should not be limiting what veterinarians can prescribe for their patients within the realm of their professional practice.

B. There is a long and ancient history of the physician practicing his healing arts, compounding chemicals to treat his patient (whether human or animal). In recognition of this fact, Congress specifically provided exemptions for the practitioners of the healing arts, and not until recently has the FDA tried to do indirectly what it is not allowed to do directly--controlling what a veterinarian may prescribe for his patient by controlling the bulk chemicals which the

veterinarian may acquire. The use of bulk drugs to compound medications has been done since the primitive beginnings of the healing arts and is absolutely essential to the practice of veterinary medicine. There is no precedent for what the FDA is attempting to do in this instance. Aee at 00033.

Veterinarians, since the beginning of their profession, have handed down compounds to each generation. Early texts on veterinary medicine dealt with compounding.[1] The training of veterinarians in compounding has literally gone on for hundreds of years and continues today in both the formal education requirements of veterinarians and in their continuing education once a veterinarian is in practice. Aee at 00027, 31, & 36.

1/Morton, D.J.T., A Manual of Pharmacy for the Student of Veterinary Medicine; containing the Substances Employed at the Royal Veterinary College with an Attempt at Their Classification, and the Pharmacopeia of that Institution(Seventh Addition, Longmans, Green, & Co. 1868).

C. It is the expressed intent of Congress that the Food, Drug & Cosmetic Act and the authority of the FDA in no way interfere with the practice of the healing arts. The congressional intent in the Act is to protect the public from harmful or ineffective products. The FDA is charged with the responsibility of carrying out the congressional intent of the Act. The legislative history, the Act, and its Amendments are replete with instances in which the practitioner of the healing arts is exempted from the requirements of the Act and the oversight of the FDA. The veterinarian falls within these exemptions. The veterinarian (along with other licensed professionals) is exempted from the purview of the Act because Congress recognized the unique relationship between the doctor and the patient and the unique responsibility which the doctor carries in this relationship. The Seventh Circuit

opinion misses the point when it discusses FDA's judgment and the necessity of following it. It is the expressed intent of Congress which the courts must follow regardless of the judgment of FDA.

In the District Court Judge Richard Mills ably and thoroughly reviewed the history of the Act, the duties of the FDA under the Act, and the power given to FDA. In the six (6) years of debate prior to the passage of the Act, the special concern of not interfering with the practice of the healing arts was thoroughly explored. Dr. Royal Copeland guided the Act through the years of congressional debate. When questioned in the Senate whether the Act would apply to medications prepared by a doctor in his practice, Senator Copeland stated, "There is noting in the bill which would interfere at all with the ordinary legal practice of the profession." 79 Cong. Rec. 5018-5019 (1935).

The statute contains exemptions for practitioners of the healing arts. 21 U.S.C. §374(a) and 21 U.S.C. §360. In subsequent amendments to the Act, Congress has had ample opportunity to amend the Act to grant power to the FDA to control the various professionals in the healing arts. Congress has not seen fit to do so and furthermore has not discussed the possibility. In 1962 Congress passed Amendments to the Act, Pub. L. 87-781, 76 Stat. 781 (1962), which granted greater power to the FDA. Although the power of the FDA was expanded by the 1962 Amendments, the exemptions for the healing arts remained. In the 1968 Animal Drug Amendments, Pub. L. No. 90-399, 82 Stat. 343, Congress consolidated provisions of the law. Again, Congress did not tamper with the protection given to the practice of the healing arts. The lower court opinion makes much adieu about the fact that there was no specific discussion about

not interfering with the healing arts when the Act was amended. Why should there have been any such discussions? For three (3) decades there had been no such interference with the healing arts by the FDA and the amendements did not limit the various exemptions for the healing arts within the Act.

The FDA has recognized it does not have the authority to interfere with the practice of the healing arts. In 1969 (shortly after the passage of the Animal Drug Amendments) a former chief counsel to the FDA stated:

The legislative history of the...Act of 1938 is replete with statements that the statute was not intended to regulate the practice of medicine. The man who guided the legislation through the Congress, Senator Royal Copeland, was a physician, and was undoubtedly concerned about interfering with his profession.... Through the six (6) years of legislative history the proposed legislation contained the affirmative requirement that every drug must bear adequate directions for use. Not only does the legislative history fail to show a congressional intent that this be used to restrict the conditions for which physicians may prescribe drugs, but it flatly contradicts any such interpretation. In enacting the 1938 Act Congress clearly intended to avoid impinging on the practice of

medicine.

Hutt, Regulation of the Practice of Medicine under the Pure Food & Drug Laws, 33 A. of Food & Drug Officials Q. Bull. 3,7 & 9 (1969). Even more telling than the comments of an attorney who represented the FDA is the final footnote of the District Court opinion below. At footnote 10 Judge Mills states:

> It is interesting to note that review of the United States Code Annotated reveals that every lawsuit brought by the United States under §321 involving new drugs or new animal drugs has involved a finished dosage drug. Clearly, the FDA is attempting to break into new areas of regulation with this as a test case.

Judge Mills is most perceptive in pointing out that the FDA is trying to break 50 years of law and mutual respect between the veterinarians and the FDA in its raw, unprecedented grab for power.

No one would argue that an individual veterinarian will never make a mistake. Neither would anyone argue that the FDA through its

bureaucratic function would never make a mistake. Congress has determined that the FDA is not to interfere with the practice of the healing arts which includes veterinary medicine. The FDA should not be allowed to circumvent this congressional intent by keeping from veterinarians bulk chemicals which they need to compound prescriptions which is exactly what will occur if the Seventh Circuit's opinion is left standing.

D. **The seized chemicals are not "drugs" subject to the power of the FDA.** The chemicals seized by the government are not "new animal drugs" because in their bulk form these chemicals are not intended for use for animals. 21 U.S.C. §321(w) provides that "new animal drug" means drugs intended for use for animals. The chemicals seized by the government are not intended for use for animals but rather must be compounded by a veterinarian before that drug which the veterinarian com-

pounds will be used. In U.S. v. Algon Chemical, Inc., No. 87-1820 (D.N.J. April 12, 1988), appeal docketed, No. 88-5478 (3d Cir. June 17, 1988), a case almost identical to the present case, the Court stated, "The language of [§321(w)] clearly indicates that the term "new animal drug" applies only to drugs which are manufactured in a finished dosage form and not to bulk ingredients used in compounding by veterinarians." The chemicals are not intended for use for animals and thus, these chemicals are not new animal drugs.

Further, 21 U.S.C. §321(w)(1) provides that a new animal drug means a drug intended for use for animals the composition of which is recognized by experts as safe and effective under the specification set forth in the labeling. As set forth in the regulations, the labeling is to address approved uses of the drug for the layman. The purpose of labeling is to

instruct the lay user of the drug on its use since the lay user is not familiar with the drug. Schuyler is neither in a position to nor could it instruct through labeling a veterinarian on how to use a particular chemical. Aee at 00018. The veterinarian must determine how that chemical will be used including the compounding of the chemical into a drug, the particular dosage to be used, and the particular treatment regimen which is to be used. Aee at 0027. "Newness" is dependent upon the labeling and frequently there are no labels at all for the medications compounded by the veterinarian, particularly those compounded in the field. Whether labeling contains "adequate directions of use" so as to avoid misbranding must depend upon for what use the chemicals are intended. U.S. v. Article of Drug Designated B-Complex Cholinos Capsules, C.A.N.J. 1966, 362 F.2d 923. Thus, the

"newness" for the animal drug and the basis for the FDA seizure is dependent upon the labeling. Labeling by Schuyler to instruct its customer, the veterinarian, is absurd.

In addition to the expressed congressional intent in the legislative history, the Act shows that the healing arts are not to be subject to the provisions of the Act or the power of the FDA. At 21 U.S.C. §374(a) the Act grants inspection authority to the FDA. Specifically excluded from such inspections at subparagraph (2) are practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propogate, compound, or process drugs solely for use in the course of their professional practice. If bulk chemicals are new animal drugs and veterinarians are unable to obtain these chemicals to compound their medications, then this exemption from inspection is meaningless. Congress could not have intended that

a physician may compound medications but may not obtain the raw materials to do such compounding. Such an interpretation of the law would be irrational. Thus, the intent of Congress to exclude veterinarians from such inspections is clear and is part of the overall intention of Congress that veterinarians not be within the regulatory authority of the FDA.

The exemption of those of the healing arts from the provisions of the Act are further shown in relationship to the registration of those who make drugs. Registration is required under 21 U.S.C. §360(a)(1) for those who make drugs. Again, as with the inspection power, the power of the FDA relating to such registration is limited in that there is an exemption for legally licensed practitioners who prescribe or administer drugs and who manufacture, prepare, propagate, compound or process drugs solely for use in the course

of their professional practice. 21 U.S.C. §360(g)(2). Exemption from registration becomes meaningless if a veterinarian must obtain FDA approval of each drug he compounds because it becomes a new animal drug. This is illogical. Necessarily if the veterinarian is exempt from registration, he must also be exempt from the FDA approval requirements. The registration exemption cannot be separated from an exemption for approvals.

The Act requires that drugs be handled under good manufacturing practices (21 U.S.C. §351(a)(2)(B)); however, the FDA has accepted that these requirements do not apply to practitioners of the healing arts. (50 Fed. Reg. 27,021(July 1, 1985)). One must not confuse the compounding of medications by the practitioner of the healing arts as allowed by the Act with manufacturing of drugs as is done by retail drug houses. One must differentiate between the professional, individual act of

the compounding of medications by the veterinarian with the mass production, consumer orientation of the manufacturing process carried on by the retail drug houses. If the veterinarian cannot obtain the raw materials, he will not be able to compound his prescriptions and there would be no need for him to be exempted from the good manufacturing practice requirements.

A final and most recent expression of congressional intent regarding whether it is to be the veterinarian or the federal bureaucracy who determines what agents will be used on food animals occurred in 1985 with the passage of the Food Security Act of 1985 in which the Secretary of Agriculture was given jurisdiction over shipments of animal biologics through licensure but veterinarians were exempted from such licensure. With the animal biologics the veterinarian is actually dealing with the disease producing organism

which may even be fatal to man yet the veterinarian is exempted from the licensing requirements when dealing with these biologics. This recent expression of congressional intent shows that Congress has determined that it is the veterinarian in whom Congress relies upon to protect the food animals rather governmental agencies.

E. The FDA regulations, when properly interpreted in light of the Act, exempt the chemicals from seizure by the FDA. 21 C.F.R. §201.122 issued by the FDA exempts bulk products from labeling requirements. 21 U.S.C. §352 provides that a drug is deemed to be misbranded unless its labeling bears adequate direction for use. But if labeling for adequate direction for use is not necessary, the Secretary (of Health & Human Services) shall promulgate regulations exempting such drugs from the labeling requirement. 21 C.F.R. §201.122 provides an exemption for

drugs in bulk from the requirement that their labeling supply adequate directions for use in compliance with §352(f). This regulation requires that the bulk materials be labeled "For manufacturing, processing, or repacking". This is the fact pattern of the instant case. The bulk materials received, repacked, and shipped by Schuyler to only veterinarians are not intended for use. But rather these chemicals must be compounded by the veterinarian into a final dosage form. Aee at 00018. Thus, the chemicals seized from Schuyler meet the criteria of this regulation for exemption of bulk products from the labeling requirement.

The FDA in its attempt to regulate the veterinary profession relies on an exception to the exemption set forth in 21 C.F.R. §201.122 to the effect that the exemption will not apply unless the one who will be using the substance has an approved new drug appli-

cation. It is the recent change in the interpretation of this exception to the exemption that FDA bases its quest for authority over the veterinarian. As has been shown the legislative history, the expressed intent of Congress in the Act, and even the admissions of the FDA all indicate that veterinarians are not subject to the Act and the authority of the FDA so long as the veterinarian is acting within the bounds of his practice. Through this new interpretation of the exception to the exemption, FDA is attempting to control how the veterinarian practices his healing art. The exeception to the exemption is not necessary to protect the public health when it relates to practitioners of the healing arts. Congress has made this group beyond the grasp of the FDA.

This new interpretation of the FDA to the exception to the exemption has been rejected by Judge Mills in his opinion for the Dis-

trict court in this case and was rejected by Judge John W. Bissell in Algon. Algon is almost identical to the instant case and both District Court judges have come to the same conclusion. The FDA is wrong.

Both Judge Mills (instant case) and Judge Bissell (Algon) carefully analyzed who had the burden of proof relating to the exception from the exemption provided by 21 C.F.R. §201.122. These judges relied upon United States v. An Article of Device: "Toftness Radiation Detector," 731 F.2D 1253(7th Cir. 1984), cert. denied, 469 U.S. 882 (1984). Both Courts found that the burden of proof would be on the claimant unless the exception to the exemption was contrary to either the letter or the intent of the law. Both judges determined that the exception to the exemption was contrary to both the letter and the intent of the statute and was not applicable to veterinarians. Judge Mills specifically

stated at Page 11 of his opinion, "The regulation is consistent with the statute to the point of exempting bulk drugs from the general labeling requirements. However, with respect to this claimant--a seller of bulk drugs to veterinarians--the limitation of the exception (i.e., that 'new drugs' are not exempt) is unreasonable and arbitrary and, therefore, a nullity." (emphasis added). Similarly the Algon court found, "The exceptions to the basic exemption are not consistent with the statute under which this regulation was promulgated. Therefore, in order to give reasonable meaning to the exempting regulation, consistent with the Act, the Court finds that only that portion which exempts bulk drugs from the labeling requirements of 21 U.S.C. §352(f)(1) applies to bulk drugs supplied for use in the practice of veterinary medicine". (Emphasis added) Aee at 00013.

F. The FDA's attempt to regulate the practice of veterinary medicine is in direct contradiction to United States Constitution. The Tenth Amendment to the Constitution states that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const. Amend. X. The regulation of the practice of veterinary medicine is a valid exercise of the police power of the states. See, e.g., Ill. Rev. Stat. 1987, ch. 111, par. 7001;[2] See also U. S. v. Cockerill, 366 F. Supp. 856 (S.D. Ill. 1973);

2/This section of the Illinois Statutes states "The practice of veterinary medicine in the State of Illinois is declared to affect the public health, safety and welfare and to be subject to State regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the veterinary profession merit and receive the confidence of the public and that only qualified and licensed persons be permitted to purchase veterinary medicine."

U.S. v. Colahan, 635 F. 2d 564 (6th Cir. 1980), cert. denied, 454 U.S. 831; U. S. v. Sene X Eleemosynary Corp., Inc., 479 F. Supp. 970 (SD Fla. 1979); Cedars North Towers Pharmacy, Inc. v. U. S., No. 77-4695 (SD Fla. 1978), printed in V. Kleinfeld & A. Kaplan, Federal Food, Drug, and Cosmetic Act Judicial Record 1978-1980 at 668; U. S. v. Evers, 453 F. Supp. 1141 (M.D. Ala. 1978), Aff'd, 643 F.2d 1043 (5th Cir. 1981); F.T.C. v. Simeon Management Corp, 391 F. Supp. 697, 707 (N.D. Cal. 1975), aff'd, 532 F.2d 708 (9th Cir. 1976); and Chaney v. Heckler, 718 F.2d 1174 (D.C. Cir. 1983), rev'd on other grounds 470 U.S. 821 (1985).

FDA's interpretation of the Act would impinge upon the regulatory schemes of the states, which license veterinarians to administer medicines in accord with professional stan-

dards.[3] The states require that the veterinarians they license exercise professional judgment in treating patients. The conflict with the requirements inherent in FDA's interpretation is apparent. To illustrate the point it would be considered inhumane to perform general surgery on a cow without using a anesthetic -- a veterinarian who attempted such surgery would be subject to discipline under state law and liable for malpractice -- yet there is no approved general anesthetic for such use, and under its current policy FDA would consider prosecution of the veterinarian should he anesthetize the cow.[4]

3/See, e.g., Iowa Code Ann. §§169.2, 169.3, and 169.13 (West Supp. 1986); La. Rev. Stat. Ann. §§1511, 1513, and 1526 (West 1974, West Supp. 1987); and Ill. Rev. Stat. 1987, ch. 111, par. 7001 et seq.

4/Some state statutes specifically mention cruelty to animals or conviction of such a crime as grounds for revocation of a veterinarian license. See, e.g., Minn. Stat. Ann. §156.081(12)(West Supp. 1987).

The manner in which FDA seeks to force veterinarians to practice would constitute incompetence and malpractice. FDA would have veterinarians treat animals only with FDA-approved drugs or refuse to treat animals altogether while the veterinarians knew of safe and effective drugs to cure these animals. Such practice would lead to the loss of many families. In addition the safe, abundant food supply which we presently know would disappear. Could the same Congress that said the Animal Drug Amendments "would not usurp any State authority" intend these results?

Agencies such as FDA may preempt state schemes of regulation, if Congress has provided for it. Capital Cities Cable, Inc., v. Crisp, 467, U.S. 691 (1984). However, preemption of state law by a federal agency is not favored, absent an expresssion of clear intention of the Congress to substitute

federal authority. Louisiana Public Service Commission v. F.C.C., 106 S.Ct. 1890 (1986); Chicago & N.W. Transp. v. Kalo Brick & Tile, 101 S. Ct. 1124 (1981).

It is not enough for the agency to argue that the action is the best way to effectuate a federal purpose. Louisiana Public Service Commission v. F.C.C., at 1901. There must be an unmistakable preemption in the congressional grant of authority in order for a regulatory agency to assume authority that detracts from a state scheme of regulation. Chicago & N.W. Transp. v. Kalo Brick & Tile, at 1130. The starting point for analysis when traditional police powers such as the regulation of the healing arts are involved is with the assumption that Congress did not intend to preempt, and that its intent to do so must by crystal clear for such an assertion to be sustained. Conference of Federal Savings and Loan Associations v. Stein, 604

F.2d 1256 (9th Cir. 1979), aff'd, 445 U.S. 921 (1980).

The authority cited by FDA for its attempt to control the practice of veterinary medicine does not meet the tests enunciated by this Court. The agency's confused approach to arrive, so many years after the Animal Drug Amendments' enactment, at this newly-announced policy underscores the lack of any congressional direction to require FDA to control the veterinarians' use of medicines. Congress never intended to make the FDA the arbiter of veterinary medical practice, and FDA cannot confer the power upon itself. Louisiana Public Service Commission v. F.C.C., at 1901.

The agency's attempt to control an indispensable, integral part of the practice of veterinary medicine without the sanction of Congress is a violation of the Tenth Amendment.

G. FDA's unwarranted efforts to control the practice of veterinary medicine will, if successful, result in a public health disaster. The partnership over the past 50 years between the FDA and the veterinary profession has resulted in a safe, abundant supply of meat, milk, and eggs. During this time the FDA has not in any manner regulated the veterinarians. This mutual partnership and respect over the past 50 years has been of great benefit to the public.

While the past has seen a harmonious relationship between the FDA and veterinarians, the FDA in its present stance has turned upon this relationship which has worked for the benefit of the consumer. There has been no activity on the part of the veterinarians nor concern about food safety which would cause concern by either the public or the FDA so as to warrant the FDA's attempt to extend its authority over veterinarians. The present

grasp for power by the FDA is unprecedented, unnecessary, and unlawful. FDA's interpretation of the Act would make it impossible to practice the healing art of veterinary medicine. There are simply not enough approved drugs. Aee at 00022. The choice is simple. Either we continue the past practice which has resulted in the best and safest supply of milk, meat, and eggs ever known to man or we follow a course of action which will imme diately result in devistation to the food producing animals.

FDA's interpretation of the Act makes it illegal for veterinarians to prescribe medications other than as directed on the label of the drugs that FDA has approved. Of the 20,000-30,000 animal drugs only 1400 are approved of which only approximately 700 are approved for the use in food animals and of which only 49 are prescription drugs used by veterinarians. The rest are sold over-the-

counter without professional supervision to layman. Essentially the FDA is delegating the veterinarian to the role of an animal undertaker for the veterinarian will be able to do little with approved drugs for approved uses except watch the animal die.

The FDA has issued a policy guide relating to unapproved uses of approved new animal drugs. The FDA has made it clear that such unapproved use of approved drugs is to occur only in rare circumstances and it will be within FDA's discretion whether to prosecute the veterinarian. This point is missed by the Seventh Circuit. In its opinion the Seventh Circuit states, "If the need is great and the risk is small, the FDA will not contend that re-mixing approved drugs, or using them in a way other than per directions on the label, causes their 'adulteration' under the acts". The Seventh Circuit cites no authority for this statement nor does it provide veterin-

arians guidance as to when the "need is great" or the "risk is small". In essence the FDA and the Seventh Circuit Court of Appeals want the veterinarian to choose on a daily basis whether to be a criminal and properly treat an animal or to ignore the professional duty of the veterinarian and allow an animal to suffer and die when known, effective treatments are available though unapproved by the FDA.

Given the fact that the number of approved drugs used in approved manners are extremely limited in food animals and the FDA and the Seventh Circuit have decided that bulk chemicals should not be made available to veterinarians to compound their own medications, the only class of drugs left out of which the veterinarian may treat animals are those drugs which were "grandfathered" under the Act so as to not need approval. While both the FDA and the Seventh Circuit speak as if

this were a major class of drugs, the truth is that the class is non-existent. In its opinion the Seventh Circuit spent a fair amount of time analyzing the words, "lawfully acquired". The conclusion of that court was that the only drugs which would meet the requirements of these words were approved drugs used in approved manners and "grandfathered" drugs. Since the requirement to use only approved drugs in approved manners is in essence the issue of this case, it is only the "grandfathered" drugs which are in fact part of the reasoning of the Seventh Circuit. That reasoning is faulty simply because the grandfathered drugs are a non-existent class. The court does note that veterinarians could not use drugs which they have stolen; however, state and federal criminal laws seem a more appropriate means of deterring the theft of drugs rather than using the seizure provisions under the Act.

The analysis of the Seventh Circuit simply makes no sense when one looks closely at the results of that analysis.

In a deposition in the Algon case, Dr. Gerald B. Guest, the Director for the Center of Veterinary Medicine of FDA could not think of a single example of such grandfathered drugs. Aee at 00045. Further, Dr. Andrew Beaulieu a Director of the FDA gave as examples of grandfathered drugs common table salt and epsom salt. Supplemental Appellant Appendix in the Seventh Circuit at 21. Are veterinarians to be relegated to administering salt solutions to pork to advance the curing process prior to slaughter and giving epsom salt foot baths to milk cows who have stood too long? While the examples are silly, they are no sillier than the positions put forward by the FDA and the Seventh Circuit regarding grandfathered drugs. Surely, Congress did not mean that veterinarians may lawfully purchase only

approved drugs for use in approved manners (and if so the exemption would not be needed) or useless items which would not provide relief to the health problems from which the patients are suffering.

H. Implementation of the Seventh Circuit's opinion by the FDA will have catastrophic effects for the American public. If the FDA is allowed to extend its authority over veterinarians by prohibiting veterinarians from obtaining the bulk chemicals to compound their prescriptions, the FDA will achieve important control over the activities of the veterinarian. Further, they will restrict veterinarian in his practice and inhibit the professional relationship between the veterinarian and his patient. The result will be simple. In uncertain situations veterinarians will not act except with the prior approval of the FDA which as the veterinarians attest will not come in a timely

manner. Aee at 00020-00042. Food animals will die and their capacities to produce food will be diminished. There will be unnecessary suffering among the food animals, there will be severe adverse effects within the agricultural economy, and the American consumer will be hurt by diminished supplies and increased prices. It is a simple fact of life that the FDA will not be able to react to the ever changing prescription needs of the food animals. Only the on-site veterinarian using his experience, education, and professional insight will be able to react to the immediate health demands of the herds and flocks of the food animals.

When a veterinarian compounds a drug (whether from pure chemicals or non-approved extra-label use of approved drugs), it is to treat a present problem. There is no time to get FDA approvals. Bacteria change and treatment needs change. The Seventh Circuit's opinion

fails to realize that the uncontradicted fact is that there is a continuing, on-going need for immediate action by the veterinarian to respond to the ever changing disease producing organisms. Drug houses which produce products to be used by the uneducated layman must do long, ongoing tests to make certain that their products are safe and effective for the use by the layman on a mass level. The veterinarian, on the other hand, is compounding his prescriptions for use in a particular instance against a particular disease organism. Even if the veterinarian could go through the FDA approval process, the approval would be meaningless since the particular problem for which the veterinarian needed the prescription would be over (and perhaps the herd wiped out).

Why should there be any variation from the past relationship between the veterinarian and the FDA? It cannot be because we are

dissatisfied with the quality or the quantity of meat, milk, and eggs. Further, control by the FDA over the veterinarian is not mandated by statute. At best the FDA is attempting to stretch the statute, enhance its authority, and control the veterinarian as has not done before. While we believe the law is clear that such a power grab is not allowed by the Act, it certainly cannot be said that the FDA has asserted this type of control previously over the veterinarian. The best the FDA can argue is that this is simply a power it has had over the last 50 years or since 1968 (the time of the passage of the Animal Drug Amendments) but has not asserted. This would certainly seem strange.

The law requires and policy dictates that the FDA not be allowed to inhibit the veterinarian from acquiring the bulk chemicals which he needs to compound his prescriptions. The future of the food supply is best served by

continuing the progress which has occurred over the last 50 years and not by placing the FDA in a position of dominance over the veterinarian.

V. CONCLUSION

A review of the Act, a review of the FDA's regulations, and a review of the intent of Congress shows a consistent approach since 1938. That consistent approach is to regulate the use of drugs in food animals by agencies of the federal government with an exemption for the licensed veterinarian to practice his healing arts. The intent of Congress, the policies embedded in the statutory provisions, and the policies carried on by the FDA for 50 years have been to place trust and confidence in the hands of veterinarians when they use drugs in the treatment of food animals. The implementation of the Seventh Circuit's opinion will subvert the intent of Congress, misapply the

law, and grant to the FDA authority which it would not have but for the misapplication of the law.

Veterinarians are very concerned. If the FDA succeeds, it will in effect control what veterinarians may prescribe by controlling what chemicals are available. The law repeatedly provides exemptions for veterinarians, and the FDA in its enforcement of the law has not previously taken a position such as the one it has in this case. Because it is bulk chemicals which were seized by the FDA, they meet the requirements of the statute and regulations as to labeling and are not new animal drugs. Further, it is ludicrous for the FDA to even imply that Schuyler should instruct veterinarians how to use the chemicals. The veterinarians are knowledgable as to the use of these chemicals, much more so than Schuyler or the FDA. Based upon the Constitution, the Act, the

regulations, the past history and conduct of the FDA, and the policy for the future, this Court should grant the Writ of Certiorari of Petitioners in order to avoid a food animal health catastrophe.

Respectfully submitted,

LE FEVRE, ZEMAN, OLDFIELD & SCHWARM LAW GROUP, LTD., Attorney for AMERICAN FOOD ANIMAL VETERINARY ASSOCIATION

BY: David Oldfield

David A. Oldfield, Esq.
LeFevre, Zeman, Oldfield & Schwarm Law Group, Ltd.
303 S. Seventh Street, P.O. Box 399
Vandalia, IL 62471
618/283-3034
File #5137/8301-4

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NO. 88-614

IN THE
SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1988

9/1 KG. CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, and SCHUYLER LABORATORIES, INC.,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES
COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF OF: Cliff Skiles, D.V.M.
Robert M. Clack, D.V.M.
1506 West Park
Hereford, TX 79045
217/285-4561

IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

Paul K. Zeman, Jr.
303 South Seventh, P.O. Box 339
Vandalia, IL 62471
(618) 283-3034

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SCHUYLER LABORATORIES, INC.,	)
Petitioners,	)
v.	) NO. 88-614
UNITED STATES OF AMERICA,	)
Respondent.	)

BRIEF OF DR. CLIFF SKILES AND DR. ROBERT M. CLACK IN SUPPORT OF PETITIONERS' PETITION FOR WRIT OF CERTIORARI

Dr. Cliff Skiles is a licensed veterinarian licensed to practice in Texas and California. Dr. Skiles office is located in Hereford, Texas. Dr. Skiles attended Texas A & M University and earned a Bachelors Degree in Veterinary Science in 1966. Dr. Skiles received a Doctor of Veterinary Medicine degree in 1967 from the same school. In 1971

Dr. Skiles received a Degree of Master of Science in Animal Nutrition from Texas Tech. Dr. Skiles practice is predominantly a large animal practice primarily beef cattle and he works with feed lot operations, farmers, and ranchers. The area around Hereford, Texas is frequently spoken of as the "feedlot capital of the world". Dr. Skiles clients have heards of variable size the largest of which is about 50,000 head of cattle. Their businesses like most farming operations are having serious economic difficulties.

Dr. Robert Clack is licensed to practice veterinary medicine in Illinois, Iowa and Colorado. Dr. Clack attended the University of Illinois and earned a Bachelor of Science degree in animal science in 1972. Dr. Clack earned a Bachelors Degree in Veterinary Science in 1974, Doctor of Veterinary

Medicine Degree in 1976 and a Degree of Master of Science in Animal Nutrition in the fall of 1976 at the same school. Dr. Clack's practice is predominantly a large animal practice of swine and beef cattle. The area around Pittsfield, Illinois used to be spoken of as the "pork capital of the world" and today it is still one of the most important centers of this activity in the United States. Dr. Clack's swine client herds vary in size up to 7000 head of swine.

Practicing veterinarians have always had a long standing successful relationship of protecting the public, the animal owner and the animals he treats. Before a veterinarian is admitted in the profession of veterinary medicine he publicly pledges the veterinarians oath. The veterinarian seldomly

swears to use his scientific knowledge and skills for the benefit of society through the:

1) Protection of Animal Health
2) Relief of Animal Suffering
3) Conservation of Livestock Resources
4) Promotion of Public Health
5) Advancement of Medical Knowledge

The veterinarian further swears to practice his profession conscienciously with dignity and in keeping with the principles of veterinary medical ethics.

It is utmost important that a Writ of Certiorari be granted because veterinarians will not only be unable to uphold the oath they have taken and will be unable to do their job if the decision in the Seventh Circuit is allowed to stand.

ISSUE

Whether the Food, Drug, & Cosmetic Act Gives the FDA Authority to Control Veterinarians?

FACTS

Animal drugs can be divided into three (3) distinct categories. The first category is the FDA approved animal drugs. FDA has only approved approximately 1400 animal drugs to treat all the species of animals that exist in America. When we contrast this to human medicine, we find that FDA has approved approximately 50,000 drugs to treat one species. This great discrepancy is due to economics and the misconception that FDA is the one that approves drugs. Alot of people believe that FDA approves drugs to take care of the disease in animals. In reality FDA leaves the drug approving process up the drug companies, and they decide based on

economics whether it is economically feasible for them to approve drugs for a disease in a species of animals.

Unlike the human world, food animal production in the U.S. is based on economics; and if the drug is too costly, the farmer can not use it. This economic fact is well understood by the drug companies, and they will simply not spend the estimated 10 million dollars and 10 years in development it takes to approve a drug unless they can justify a return on their investment. As a result of this economic fact, the drug companies have only approved 1400 drugs for all animals that exist in America. To say the least there are alot of species of animals and alot of disease in animals with no drugs approved for them. In very simplistic terms there is

no way a veterinarian can do his job with only 1400 approved animal drugs to work with.

It is even more alarming when we break the 1400 approved animal drugs down into the ones approved for food animals. FDA has only approved around 700 drugs to treat the food animals with of which only 49 are controlled by the veterinarian. This means that out of the 700 drugs approved for food animals 651 are sold freely over the counter to anyone in the U.S., herein referred to as OTC. This means that FDA is allowing 93% of all the approved food animal drugs to be manufactured and sold directly to livestock producers for use directly in food animals without any veterinarian supervision. What has resulted over the last 30 years of FDA allowing indiscriminate use, over use and

misuse of approved food animal drugs by the livestock producer diagnosing and treating their own animals is infectious diseases have developed resistance to the FDA approved food animal drugs rendering them ineffective for theraputic use in treating disease conditions in food animals.

The second category of animal drugs is FDA's Unapproved Animal Drugs. In the 27th report in 1985 by the Committee on Government Operations CVM officials stated, "FDA has failed to regulate the distribution and use of unapproved new animal drugs. CVM officials believe that as many as 90% or more of the 20,000 to 30,000 new animal drugs estimated to be on the market have not been approved by FDA as safe and effective and, therefore, are being marketed in violation of the new animal drug approval

requirements of the Food, Drug, and Cosmetic Act. It is estimated that as many as 4000 of these new animal drugs may have "potentially significant adverse effects on animals or humans". This means that FDA is allowing drug companies to freely manufacture and sell an estimated 18,000- 27,000 animal drugs that have never been approved. It is even more alarming when one realizes that FDA is allowing all these drugs that have never been approved to be safe and effective to be manufactured and sold freely OTC to anyone without any veterinary supervision.

So we have the federal agency who is charged with assuring that drugs are to be safe and effective before they are freely marketed to protect the public from residue in our meat milk and eggs sanctioning the illegal man-

ufacture and distribution OTC of unapproved animal drugs. The FDA funded by our U.S. tax dollars is allowing drug companies to break the law and endanger the public with residue in our meat, milk and eggs. Again, from the infectious disease standpoint what has happened by FDA allowing these unapproved drugs to flow freely OTC during the last 30 years is infectious diseases have developed resistance to these unapproved drugs rendering them ineffective in most cases.

The third category of animal drugs is veterinarians compounding medicine to be administered and prescribed in the course of their professional private practice. There is no way of knowing how many drugs are represented in this category because these drugs are private prescriptions between the

veterinarian and his client and they will change as the disease condition dictates. This category of drugs are also not approved by the FDA, but this category is legal as all practitioners of the various fields of healing arts are exempt from the FDA approval process.

When Congress passed the 1938 Federal Food Drug & Cosmetics Act at Section 510[360](g)(2), they very wisely exempted all practitioners from registering with the FDA and going through the drug approval process at Section 510[360](g)(2) when, "Practitioners licensed to by law to prescribe and administer drug and devices and who manufacture, prepare, propogate, compound, or process drugs and devices solely for use in the course of their professional practice". Congress very

wisely recognized that the drug approval system they had enacted was very time consuming and costly and would be out of the grasp of health practitioners. They recognized that patients and the diseases that affect them are not static and fixed like the FDA drug approval system so they left flexibility in the system so the members of the healing arts could protect the public and patients.

With years of formal education and state licensure accompanying each member of the healing arts, Congress felt comfortable that the public would be safely protected in granting this exemption to the practitioners of the healing arts.

FACTUAL CONSEQUENCES IF A WRIT OF CERTIORARI IS NOT GRANTED

I. Due to FDA's policies of allowing almost all of the approved animal drugs and all of the unapproved animal drugs to be freely sold OTC over the last 30 years, infectious diseases has developed resistance to these drugs. In contrast, in human medicine 99.6% of all the 50,000 drugs are first of all approved & secondly all drugs and vaccines that are used to treat infectious diseases are under the direct supervision of the physician.

As a result in human medicine you do not have the widespread drug resistance to infectious diseases as you do in animal medicine. So as the result of this widespread drug resistance that has

developed in the animal world, veterinarians more than ever today must purchase the chemicals to compound into medicinse to treat the infectious diseases that are resistant to FDA's approved and unapproved animal drugs. If veterinarians are no longer allowed to purchase chemicals to compound their own effective medicine, then animals will suffer, die and the public health will be put in jeapordy.

II. There are approximately 250 diseases that can spread from animal to man. Veterinarians work directly with the livestock producer are in the best position to stop the disease transfer from animal to man. Many of these diseases have no drugs approved to treat them with and many of these diseases are also resistant to FDA's approved and unapproved animal drugs. If

veterinarians cannot purchase chemicals to compound his own effective medicine to treat these diseases they can spread to man and threaten the public health.

III. Diseased food animals will enter the stream of commerce and threaten public health. With the Seventh Circuit's decision if a farmer has a herd of animals infected with a disease and they are dying because FDA's approved and unapproved drugs are not working and the farmer does not have the option of veterinarians compounding medicine to treat his animals, the livestock producer will sell the infected animals that are in the early stage of infection to slaughter. Most animals in the early stage of infection will pass the ante-mortem inspection at most slaughter facilities resulting in diseased

animals entering the stream of commerce endangering public health.

IV. With widespread practice of "factory farming" the raising of food animals in large masses designed to maximize economy of scale, what has resulted is impaired immunity in farm animals due to increased stress. With immunity lowered the animals defenses are decreased resulting in an animal that is very susceptible to acquiring a disease and the disease spreading throughout the herd. Most of the time the farm has already tried the approved and unapproved animal drugs and they are not working, so the veterinarian has no other option than to compound more powerful drugs or combinations thereof from chemicals to treat the animals. If chemicals are not available for veterinarians to compound the

net result will be loss of livestock resources, animals will die and suffer.

V. FDA and the drug companies have not approved enough drugs to treat the diseases in the species. In the majority of species of animals that exist in America there are very few and in many species of animals there are no drugs approved to treat the diseases at all. Please see the affidavits filed by the veterinarians in this case found in the Supplemental Appendix of Appellees filed in the Seventh Circuit.

VI. The majority of all drugs that FDA and the drug companies are marketing that are approved and unapproved are drugs that are already compounded. In 98% of the cases if the veterinarian can only purchase compounded approved animal drugs from a drug

company he cannot use them to compound his own medicine because the carriers, vehicles and extenders that one drug company uses to compound the approval animal drug in most circumstances are not compatible with the carriers, vehicles and extenders that another company uses to compound their approved animal drug. So FDA knows if they can keep the pure chemicals out of the hands of the veterinarian then they will essentially stop all veterinarians from compounding. If veterinarians cannot purchase pure chemicals to compound medicines; then animal health will be in danger, animals will suffer, we will lose livestock resources, public health will be in danger, and advancement of medical knowledge will almost come to a stop.

VII. FDA and the drug companies have not

approved all drug formulations to be used in all acceptable dosing regiments. As the result if veterinarians cannot purchase pure chemicals to compound medicine the use of valuable drugs would be very limited. For instance FDA and the drug companies have only approved the use of the valuable antibiotic polymyxin for only ophthalmic ointments. If the veterinarian diagnosed a disease that required polymyxin to be injected into an animal, the formulation that FDA and the drug companies have approved are not suitable for such uses. The net result would be if a veterinarian cannot purchase polymyxin as a pure chemical to use in compounding medicine other uses for this valuable drug would not be available to the animal world.

VIII. FDA and the drug companies have <u>not</u>

approved the drugs to be used in all species. For instance the valuable drug cephapirin is the only approved for intramammary infusion in the cow. If a veterinarian wanted to use cephapirin in the pig, dog, cat, sheep, birds, or any other specie it cannot be used under FDA's and the drug company's approval system because they have only approved it for the cow and even more specific only for intramammary infusion in the cow. Again, as noted in Number VII you cannot take a product formulated for intramammary infusion and inject it into an animal. The intramammory formulation is not compatable for injection purposes. As a result if the veterinarian cannot purchase cephapirin as a pure chemical to use in compounding medicine, other valuable uses of this drug would not be available to the animal world.

IX. If the Seventh Circuit's decision is allowed to stand it will have negative consequences to many advances in human medicine and knowledge. Many advances in human medicine are gained from the knowledge of clinical studies on sick animals. Human diseases such as cancer and immune-deficiency extensively use animals in their research to help discover a cure for these diseases.

X. In just the last 10 years we have seen the following new diseases develop in swine industry which are:

Strepptococcus Suis Type II
Leptospira Brataslava
Haemophilus Parahemaliticus
Haemophilus Suis

Clostridium Type C
Coccidiosis

Strepptococcus Suis Type II has killed several slaughter plant workers when it first developed into a disease. We hate to think what would have been the outcome to the public and the animal world if veterinarians could not compound medications to treat these diseases. This is not an uncommon occurrence. As you can see from the new diseases that have developed in swine in just the last 10 years. If veterinarians do not have the tools available to work quickly the results will be disasterous.

If the veterinarian had waited the 10 year average for FDA and the drug companies to approve drugs for these diseases; the loss

would have been disasterous for the farmer, the suffering animal, and the public health. Who knows what new disease will develop in the future? If we put complete control in the hands of the FDA, we could lose species of animals and likewise the threat to humans would be great. What FDA is proposing is that the educated and trained veterinarian wait for FDA and a drug company to approve a specific drug formulation for each specific species of animal and disease condition even though the veterinarian has been educated and trained to effectively treat the disease and even though the chemicals are already approved and being used by the drug companies in the U.S.

We are not talking about the veterinarians purchasing chemicals that have never been approved for use in this country or chem-

icals that have been banned for use in food animals. We are talking about veterinarians purchasing the active drug ingredient in pure form of drugs FDA already have approved and for the veterinarian to use their chemicals in compounding medication for the protection of the public, the livestock industry and the animals that exist in America because FDA has not done their job.

THE LAW

Section 360 is the registration of producers of drugs and devices of the Federal Food, Drug & Cosmetic Act. At (g) in this Section Congress specifically enacted that "the foregoing subsection of this section shall not apply to-

> (2) Practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propogate,

compound, or process drugs and devices solely for use in the course of their professional practice.

(3) Persons who manufacture, prepare, propogate, compound or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale.

Enclosed is the catalog from Sigma Chemical Company. This catalog contains over 21,000 chemicals. In the 1987 List of FDA Approved Animal Drug Products by Richard B. Talbot of Virginia Polytehnic Institute & State University, Section 5 is a list of FDA's Selected Active Ingredients of the Approved Animal Drug Products. There are 291 Selected Active Approved Animal Drug Ingredients and

over 50% of these drug ingredients can be found in the Sigma catalog. In the FDA Regulatory Procedure Manual, Part 9 is FDA's 1983 Import Alert Policy entitled Bulk New Animal Drug Substances, FDA lists 50 New Animal Drugs and 86% of these New Animal Drugs can be found in the Sigma catalog. The Sigma catalog also contains a vast number of the chemicals used in the U.S. plus toxic chemicals, chemicals that are known cancer producing agents, and controlled substances.

The question is are these chemicals drugs when a veterinarian purchases them. The answer to this question can be found in Section 201. The definition section of the Federal Food, Drug & Cosmetic Act defines the term "drug". This section defines the term "drug" at (B) as "articles intended for use in the diagnosis, cure, mitigation, treat

ment, or prevention of disease in man or other animals."

When a doctor purchases a chemical no one knows if he intends to use that chemical on or in an animal. Only when the doctor compounds or formulates the chemical and prescribes or administers it in or to be used in or on an animal or man is anyone certain that the doctor intends to use the chemical as a drug. Again as we refer back to Section 510[360](g)(2) we find that Practitioners of the fields of healing arts do not have to register with the FDA as producers of drugs and devices and go through FDA's new animal drug approval process. If the Seventh Circuit decision is allowed to stand, FDA will have the law defined to say that all chemicals are new animal drugs and before a doctor can purchase a checmical which is a

"new animal drug" he must first get it approved if he is a member of the field of healing arts.

If the Seventh Circuit is not reversed, all chemicals purchased in the enclosed Sigma Chemical Catalog or any other company such as common limestone (calcium carbonate) on Page 361 and table sugar (sucrose) on Page 1302 will have to be approved by the FDA before a veterinarian can purchase them. Even if a veterinarian intended to prescribe or administer these chemicals in animal feed, as a nutritional additive, FDA could stop the purchase by a veterinarian because FDA would have all chemicals defined as "new animal drugs" when purchased by members of the healing arts. The animal industry and the human world consider both limestone and sugar to be normal requirements or additives of the

every day diet of animals and humans, but FDA would have the law to state otherwise if the Seventh Circuit decision is not overturned.

The real irony of the whole situation is that FDA recognizes that teachers, chemists and other laymen are exempt at Section 510[360](g)(3) from registering as producers of drugs and devices and freely allows them to purchase all the chemicals in the Sigma Catalog even the products that FDA claims as drugs even the products FDA claims as "new animal drugs", but when it comes to veterinarians FDA says they do not fall in this exemption at Section 510[360](g)(2) and veterinarians have to approve everything the veterinarian prescribes or administers.

FDA is very inconsistent in interpreting the law as it applies to veterinarians and FDA is

discriminating against veterinarians. If the Seventh Circuit decision is allowed to stand, it will not be the animal drug industry that is turned upside down as FDA claims but it will be the veterinarian medical profession and the animal industry that it turned upside down. As complete control of prescribing and administering drugs will be placed in the hands of FDA and the drug companies approval system. The veterinarian will be separated from the animal owner, the public will suffer and the animal industry will suffer. In essence, the few benefits that such a restrictive regulatory policy would have is far outweighed by the harm that such a policy would have on animal industry and the public.

Veterinarians Need to Purchase and Use Chemicals, Not as Drugs to Treat Animals, In Order to Do Their Job FDA's assumption is that whenever a veterinarian purchases chemicals he intends to use these chemicals as a drug in treating animals. Dr. Gerald Guest of the FDA in deposition could not think of any chemical that was not a new animal drug. Supplemental Appendix of Appellees filed with Seventh Circuit at Page 45. Dr. Andrew Beaulieu of the FDA in deposition could only think of two (2) drugs that were not new animal drugs which were sodium chloride (common table salt) and epsom salt. Appellant Appendix in the Seventh Circuit at Page 21. Since FDA's position is that essentially all chemicals are new animal drugs the veterinarian will have to approve all chemicals he purchases except sodium chloride and epsom salt. If the Seventh

Circuit decision stands, FDA will be bound by law to stop all chemical purchases by a veterinarian except perhaps the purchase of sodium chloride & epsom salt. Veterinarians cannot do their job without pure chemicals. Examples follow:

1. The veterinarian today is a multi-faceted individual that is involved in every area of animal rearing. Nutritional recommendations, prescribing and administration are common place to most veterinary practices. Alot of the daily recommended nutritional requirements are chemicals such as minerals, true minerals and vitamins. If the Seventh Circuit decision stands the veterinarian would not be allowed by law to purchase the nutritional chemicals whereas any

non-veterinarian could freely purchase and recommend usage of these chemicals.

2. Many of veterinarians are involved in semen collection and insemination. After the semen is collected from an animal, it is mixed with extenders that prolong its life outside the animals body and facilicate the fertilization process once it is inseminated into the female animal. The extenders are made from chemicals. Pure chemicals or drugs have to be used in the extenders for if an approved drug is used the vehicles, carriers and extenders that are used by the drug company in compounding the approval drug will kill the semen. If the Seventh Circuit decision is allowed to stand, non-veterinarians will be allowed to purchase and use such

chemicals but by law veterinarians will not.

3. A large number of veterinarians have their own diagnostic laboratory, bacteriology laboratory, nutritional laboratory, and etc. These laboratories cannot function without the use of chemicals and they require different chemicals to function. For instance some veterinarians choose to make their own antibiotic sensitivity disc. In order to do this the veterinarian must buy pure drugs or chemicals free of extenders, carriers, and vehicles. If the Seventh Circuit decision stands, veterinarians by law would not be able to purchase these chemicals but non-veterinarians could do so.

4. Veterinarians use alot of chemicals in there every day routine practice, but not as drugs in treating disease conditions. Some such uses would be disinfectants, cleaning agents, antiseptic agents, and regents. If a veterinarian uses a chemical that is traditionally thought of as a drug, as a disinfectant is it a drug or a chemical? If the Seventh Circuit decision is allowed to stand, FDA by law will recognize it as a new animal drug and stop the veterinarian from purchasing the chemical. Again non-veterinarians would be allowed to purchase the chemicals.

CONCLUSION

If FDA is allowed to control the chemicals and the compounding of medicines by the licensed veterinarian, then the results will

be veterinary medicine controlled by the FDA and the drug companies. This would result in a profession that will be reduced to trained professionals reading labels and counting pill doses to his clients. This would result in the loss of the art of medicine, clinical knowledge and advancement of veterinary medicine. This will result in the animal owner purchasing the same drugs as the veterinarian, reading the same labels, and counting the same pills and doses. This will result in the separation of the veterinarian from the animal owner. (There will be no need for licensed veterinarians if the animal owner can purchase and administer essentially everything that a veterinarian can). This will result in decreased protection of animal health, increased suffering in animals, decreased conservation of livestock resources, decreased promotion of public

health and decreased advancement of medical knowledge. The harm of such a policy have be devestating to the animal world, our food supply and public health. For all the reasons set forth in the Brief of Petitioner Schuyler Laboratories, Inc. this Court should exercise its discretion to review the decision reached by the Seventh Circuit Court of Appeals.

Respectfully submitted,

/s/Cliff Skiles, D.V.M.

/s/Robert M. Clack, D.V.M.

1506 West Park
Hereford, TX 79045

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On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

PETITIONERS' REPLY BRIEF

JAMES R. PHELPS
(Counsel of Record)
ROBERT A. DORMER
HYMAN, PHELPS & MCNAMARA, P.C.
1120 G Street, N.W.
Washington, D.C. 20005
(202) 737-5600

Attorneys for Petitioners

Balmar Legal Publishing Division, Washington, D.C. (202) 682-9800

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No. 88-614

IN THE

Supreme Court Of The United States

OCTOBER TERM, 1988

9/1 KG CONTAINERS, MORE OR LESS,
OF AN ARTICLE OF DRUG FOR VETERINARY USE,
AND SCHUYLER LABORATORIES, INC.,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

PETITIONERS' REPLY BRIEF

I. INTRODUCTION

The brief for the United States in Opposition ("Gov. Br.") must be read closely to find acknowledgment of the statutory theory upon which the government proposes to regulate the practice of medicine. Only on the fifth page does the brief recognize that the bulk drugs are for use in the veterinarian's treatment of animals. It is not easy to see that the government proposes to secure, through the Seventh Circuit decision, the novel authority to insert itself between each patient and practitioner to preclear every use of medicine by the practitioner.

The government never forthrightly acknowledges the mechanism it seeks to employ to regulate the bulk drugs. The sole reason that the bulk drugs are considered "new" by the Food and Drug Administration ("FDA"), and therefore the reason why they would require premarket approval, is the way that they are to be

used by veterinarians in their practices. FDA contends that each and every use of a medicine by a veterinarian is subject to the preclearance authority procedure established in the Federal Food, Drug, and Cosmetic Act ("Act") for "new" drugs.[1] In other words, it is not sufficient that bulk drugs used in medical practices be pure and of the proper strength. The government asserts that FDA must know about each use with each patient, and that the new drug approval process must be employed to approve each such use in advance. The government asserts nothing less than this, but declines to say so in its brief.

This theory, sustained by the Seventh Circuit[2] and rejected by the district court below[3] and the district court in *Algon*,[4] means that no medicine may be used by any veterinarian until and unless some commercial enterprise has seen fit to secure approval of a drug from FDA. The government's brief does not even acknowledge this. Beneath the recitations about the good purposes of the Act, the predictions of its demise and unsubstantiated threats to health unless the bulk drug regulation can be used as FDA proposes, the government is seeking a radical revision of the historical relationship between itself and the practice of medicine. Under this new scheme the decisions made in the doctor/patient relationship are subordinated to FDA. The district court saw this. The Seventh Circuit saw it too, but, looking past the legislative history of the Act and prior precedents, decided that the government should have control over how practitioners use medicines.

Perhaps the reticence of the government to describe the basis of its case and the implications of the Seventh Circuit's ruling derives from their conflict with the current regulatory system. The task of this reply then is to explore some remarkable omissions and obfuscations.

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[1] Gov. Br. at 4-5 (discussing 21 C.F.R. §201.122 (1988)).

[2] *United States v. 9/1 Kg Containers*, 854 F.2d 173, 179 (7th Cir. 1988), Appendix to Schuyler Petition ("App.") at 9a.

[3] *United States v. 9/1 Kg Containers*, 674 F. Supp. 1344, 1348-1349 (C.D. Ill. 1987), *rev'd*, 854 F.2d 173 (7th Cir. 1988), App. at 19a-20a.

[4] *United States v. Algon Chemical Inc.*, 689 F. Supp. 394, 399-400 (D.N.J. 1988), *appeal docketed*, No. 88-5478 (3d Cir. argued Jan. 9, 1988), App. at 42a-43a.

II. MEDICAL PRACTICE AND THE ACT CAN COEXIST

A. The Act Will Not Be Circumvented

Without saying exactly how, the government twice asserts that unless the agency can exert prior approval authority over each medicine used by practitioners, then the entire system of FDA approvals would collapse. Gov. Br. at 8 and 16. The government argues that without this power over all medicines, the system for regulating bulk drugs would be undermined, meaning that manufacturers will simply sell bulk products and stop making final dosage products. It should be a sufficient response to say that the basic regulatory system has continued in service for over fifty years since the passage of the Act without FDA asserting this new authority.

There is however another potent reason why the use of bulk drugs by practitioners to make their own medicines will not destroy the FDA's drug approval system. The reason is advertising. No one can deny the importance of advertising in the pharmaceutical business. FDA's regulations expressly recognize that bulk drugs, including drugs for prescription compounding, can be advertised and sold but that no therapeutic claims can be made for such bulk products. 21 C.F.R. §§202.1(e)(2)(ii) and (iii) (1988).[5] If any therapeutic claim is made for a bulk drug product, then that will make it subject to being considered "new" and prior agency approval of the product for that use would be required. Pharmaceutical houses are only too willing to be regulated and to pass products through the new drug clearance procedure in order to advertise their products for approved uses.

B. The Public Will Be Protected

Not only will the regulatory system not collapse, it can continue to function appropriately to protect the public health without giving FDA the power to practice medicine. The government says that nothing in the legislative history of the Act suggests that "misbranded or adulterated bulk drugs, or drugs that are deemed dangerous or ineffective by the FDA" may be shipped

[5] Section 202.1(e)(2)(iii), entitled "Advertisements of prescription-compounding drugs," again shows that FDA has in the past and currently recognizes the need for compounding of medicines.

"simply because the recipient is a veterinarian." Gov. Br. at 9. Petitioner, Schuyler Laboratories, Inc. ("Schuyler"), has never contended that the Act allowed such activity. The agency is now and always has been able to stop the shipment of any misbranded or adulterated drugs, and any drugs that it considers dangerous or ineffective.

If FDA considers any drug to be dangerous, either because of the harm it does or the harm it might do because it is ineffective, then it can stop any health care practitioner from receiving that drug. For example, the bulk drug regulation at issue here, 21 C.F.R. §201.122, does not exempt bulk drugs from Section 502(f)(2) of the Act, 21 U.S.C. §352(f)(2)(1982). Under that provision, the FDA could prevent a bulk drug from being shipped if its labeling did not provide adequate warnings against conditions in which its use "may be dangerous to health, or against unsafe dosage or methods or duration of administration or application ...."

Also, bulk drugs are not exempt from Section 502(j) of the Act, 21 U.S.C. §352(j) (1982), which deems a drug, including a bulk drug, to be misbranded if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." If the labeling said "for compounding by a veterinarian" and use by veterinarians were dangerous, as FDA asserts is the case with some drugs such as dimetridazole,[6] then FDA could of course intervene under the existing law. FDA could cause the seizure of the drugs, enjoin their shipment, or even prosecute persons responsible for such shipments. 21 U.S.C. §§331-334 (1982).

The law also requires that all drugs -- bulk or finished form, approved through the "new drug" process or unapproved -- be made under good manufacturing conditions, and that they be pure and of proper strength. 21 U.S.C. §351(a)(2)(B) (1982); 21 C.F.R. Part 211 (1988). Drugs that fail to meet such requirements, including bulk drugs, are legally adulterated. *Id.*

There is therefore no need for the government to extend its authority into the practice of medicine in order to protect the

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[6] Gov. Br. at 14 n.13.

public from unsafe medicine. FDA has ample regulatory powers to protect the public health without requiring prior approval of every use of a drug by a veterinarian.[7]

C. Public Health Requires That Practitioners Be Allowed To Treat Their Patients Without Federal Interference

The argument that the public safety requires that the government should be the referee to decide how the healing practitioners may treat each patient is empty, contradicted by the history of agency practice and inconsistent with the clearly expressed intent of Congress. As this Court stated in a different context in *Bowen v. American Hospital Association*, ____ U.S. ___, 106 S.Ct. 2101, 2121 (1986), "Congress has failed to indicate, either in the statute or in the legislative history, that it envisioned federal superintendence of treatment decisions traditionally entrusted to state governance." This conclusion applies with equal force here.

The falsity of the government's argument is made apparent by the uncontradicted statements of veterinarians who establish the harm to food animals if they cannot be treated until the pharmaceutical houses decide to gain FDA approval for the animals' afflictions.[8] The *amicus* briefs of the Humane Society of the United States and the American Food Animal Veterinary Medical Association eloquently describe the harm that will result if the Seventh Circuit's decision is sustained. The irrationality of the government's argument is made palpable by the admission of the head of FDA's Center for Veterinary Medicine that the agency's interpretation of the Act will force veterinarians to choose between adherence to professional ethics or exposure to criminal liability.[9]

The Seventh Circuit expressed considerable skepticism about the ability of physicians, veterinarians, and other medical professionals to employ drug therapy without a Washington guide.

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[7] The controls affecting veterinarians are described in Schuyler's Petition for Writ of Certiorari ("Schuyler Petition") at 29.

[8] This record was discussed in the Schuyler Petition at 6-7.

[9] Guest Deposition, Appellees' Supplemental Appendix filed in the Seventh Circuit (Appellees' App.) at 69-71.

This skepticism was not shared by the Congress, as the legislative history shows. Schuyler Petition at 8-18. Nor is this skepticism shared by FDA.[10] And other courts of appeals have observed the *necessity* for medical practitioners to use medicines in a manner not approved by FDA.[11] Further, the record in this case demonstrates that training to compound and use medicines is part of the routine professional training of veterinarians.[12] The Act contemplates that manufacturers of "new drugs" need prior approval for their products, but the Act does not equate that kind of business with the professional task of using medicines to treat patients.

III. UNAPPROVED USE VERSUS BULK DRUG USE

The government in many places refers to the distinction between the use of approved drugs for unapproved purposes and the use of bulk drugs, for which there is no approval. This is a distinction without a difference. It is important to repeat that drugs that have gone through the new drug approval process and those that have not are subject to FDA's requirements for good manufacturing, purity, strength, and proper labeling. Thus, the consequences of using drugs for "unapproved" uses are indistinguishable, except that pure bulk drugs are usually easier to use for compounding purposes because they do not have unwanted or difficult active or inactive components that finished drug products have blended in them.[13]

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[10] *See, e.g.*, Compliance Policy Guide 7132.06, "Hospital Pharmacies - Status as Drug Manufacturer," Exhibit K to Claimant's Memorandum in Opposition to Plaintiff's Motion for Summary Judgment and in Support of Claimant's Motion for Summary Judgment (where FDA states that hospital pharmacies may compound unapproved medications on a physician's order without obtaining clearance under the "new drug" provisions of the Act).

[11] *Grinspoon v. DEA*, 828 F.2d 881, 887 (1st Cir. 1987); *Chaney v. Heckler*, 718 F.2d 1174, 1180 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985).

[12] *See, e.g.*, Biehl Statement at ¶¶4-5, Appellees' App. at 20; Clack Statement at ¶¶3, 4, and 7, Appellees' App. at 22-24.

[13] Clack Statement at ¶9, Appellees' App. at 25; Skiles Statement at ¶7, Appellees' App. at 32. The government says FDA does not "usually" approve bulk drugs. Gov. Br. at 2. In fact, it never approves bulk drugs and has no procedure to do so; this means that no bulk drug, though pure and of proper strength, is ever "approved" through the new drug clearance procedure.

FDA has expressly recognized that the use of approved drugs in an unapproved manner is not regulated by the Act if done within the scope of a *physician's* practice. 37 Fed. Reg. 16,503 (1972); 52 Fed. Reg. 8798, 8803 (1987).[14] *See also, United States v. Evers*, 643 F.2d 1043, 1048 (5th Cir. 1981), where the agency acknowledged the legality of such prescribing under the Act. FDA has not, however, attempted to explain how the use of a bulk chemical to treat patients is outside of the practice of medicine. The Seventh Circuit's opinion makes no distinction between the unapproved use of approved drugs and the use of bulk drugs, or the use of such drugs by one kind of practitioner or another.[15] According to the Seventh Circuit, the Act prohibits all licensed practitioners from using any drug for an unapproved purpose and thus empowers FDA to regulate the treatment decisions of all licensed practitioners. 854 F.2d at 176-177, App. at 5a.[16]

IV. THE CITED AUTHORITIES AND IGNORED PRECEDENTS DO NOT SUPPORT THE SEVENTH CIRCUIT'S DECISION

The authorities ignored by the government and even the authorities cited in its brief contradict the theory that the Act empowers FDA to preclear each and every use of a medicine by practitioners.

The Seventh Circuit and the government in its briefs below and here have paid little attention to the legislative history of the Act. Yet that history is clearly and totally contradictory to the

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[14] The government argued in the district court and in the court of appeals that the Act requires that veterinarians, but not other practitioners, use drugs only for their approved purposes. Plaintiff's Memorandum in Opposition to Claimant's Motion for Summary Judgment at 11-15; Reply Brief for the Appellant at 11-12. Thus, according to FDA, physicians when treating humans can use approved drugs for unapproved purposes, but veterinarians when treating animals cannot.

[15] The Seventh Circuit does, however, misread the agency's promise to consider regulatory action against veterinarians who use approved drugs in an unapproved manner as a "non-enforcement policy." *United States v. 9/1 Kg Containers*, 854 F.2d at 178, App. at 7a-8a; Schuyler Petition at 27.

[16] The Seventh Circuit ruling applies with equal force to the prescriptions compounded by pharmacists and physicians. Therefore, they would not be entitled to receive bulk drugs for compounding.

authority that they seek to give the government over the healing professions.

The most thorough, recent analysis of the legislative history appears in the court of appeals' opinion in *Chaney v. Heckler*, 718 F.2d 1174 (D.C. Cir. 1983), *rev'd on other grounds*, 470 U.S. 821 (1985). Schuyler has discussed this opinion in its petition. Schuyler Petition at 19-20. Ignoring the court of appeals' analysis at pp. 1179-1180, the government cites those pages for the proposition that "FDA had the authority to limit the uses that a physician could make of an approved drug." Gov. Br. at 17. Yet the ignored analysis recognized the "practice-of-medicine" exemption and provided a detailed explanation for doing so.[17]

This readily acknowledged exemption -- from the new drug approval process, not the Act itself -- is of course the very exemption that the Seventh Circuit found did not exist. It is therefore no wonder that the government deals with the *Chaney* decision by not addressing this vital component of it. Further, only by ignoring the *Chaney* analysis, the legislative history, and other decisions is it possible for the government to argue, as it has, that there is no split of authorities among the circuits. Gov. Br. at 16-17.[18]

The government also misstates the holding of *United States v. Rutherford*, 442 U.S. 544 (1979). Gov. Br. at 11. To say that the Court "held" that physicians might not obtain Laetrile for use in terminally ill patients without FDA's prior approval is to extend the holding into an area that the Court simply did not explore. The issue of the practice of medicine and its relationship to FDA's authority was not considered in the Court's opinion. The opinion and the arguments presented to the Court related to the applicability of a right of privacy to permit the patients to receive un-

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[17] The government also ignores the finding made by the court of appeals that "*(n)onmedical* use of lethal injections ... cannot fall within the 'practice-of-medicine' exemption ...." 718 F.2d at 1180. (Emphasis added.)

[18] The government's brief also distorts the precedent of *United States v. Evers*. The rationale of that case, and the recognition in it -- by the Fifth Circuit and the FDA -- that FDA is not empowered to regulate treatment decisions of practitioners, are in no wise diminished by the fact that the drug involved was "a prescription drug prescribed and dispensed by a licensed physician ...." Gov. Br. at 17.

approved drugs. The Court's rejection of that argument does not eradicate the "practice-of-medicine" exemption. Note, however, that the exemption would not prevent FDA from halting the shipment of quack remedies such as Laetrile to practitioners in bulk or finished form. 21 U.S.C. §§352(f)(2) and 352(j).

V. THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE VIRUS-SERUM-TOXIN ACT SHOULD BE INTERPRETED TOGETHER

The government dismisses the Virus-Serum-Toxin Act ("V-S-T Act"), saying that it "is an entirely separate law and supplies no assistance in interpreting the provisions of the FDCA [Federal Food, Drug, and Cosmetic Act]." Gov. Br. at 15. The V-S-T Act, which requires the prior federal approval of animal biologics, expressly exempts from such approval requirements biologics prepared by a veterinarian for use in his or her practice. 21 U.S.C. §154a(2) (Supp. IV 1987). The government's argument ignores several salient facts. First, animal biologics, whether subject to premarket approval or exempt from such requirement, are nevertheless "drugs" under the Federal Food, Drug, and Cosmetic Act and therefore subject to the adulteration and misbranding provisions of that Act. *Grand Laboratories, Inc. v. Harris*, 660 F.2d 1288 (8th Cir. 1981), *cert. denied*, 456 U.S. 927 (1982). Therefore, FDA can take enforcement action against a veterinarian who compounds an adulterated or misbranded biologic notwithstanding that the product is exempt from premarket approval.

Second, the Federal Food, Drug, and Cosmetic Act provides that it shall not be construed "as in any way affecting, modifying, repealing, or superseding the provisions of ... the virus, serum, toxin, and analogous products provisions, applicable to domestic animals ...." 21 U.S.C. §392(b)(1982). If the two statutes were "entirely separate" as the government contends, this provision would have been unnecessary.

Third, FDA's regulations expressly exempt from the approval requirements of Section 512 of the Act, 21 U.S.C. §360b, "[a]n animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law ... and any regulations issued thereunder ...." 21 C.F.R. §510.4 (1988). The regulation

does not, however, exempt animal biologic drugs from other requirements of the Act.

Where two statutes deal with the same subject, as here, they should be interpreted together. Sutherland Stat. Const. §51.02 (4th Ed.). Where there are several possible interpretations of a statute, the one which produces a reasonable result is favored. *American Tobacco Co. v. Patterson*, 456 U.S. 63, 71 (1982). The result advocated by the government here is without question unreasonable. The government has not even attempted to explain what rationale or public policy supports its theory that Congress intended to exempt veterinarians from premarket approval when they compound their own biologic drugs, such as vaccines, but that Congress intended to require veterinarians to obtain federal approval to engage in the very same activity with non-biologic drugs. Rather the government makes the unconvincing argument that "Congress knows how to exempt veterinarians from premarketing approval requirements when it wishes to do so ...." Gov. Br. at 15.

VI. CONCLUSION

The conflict of the Seventh Circuit's decision with all preceding interpretations of the status of the healing professions under the Act warrants this Court's review. The Act is intended to protect the public by preventing unsafe drugs from reaching the market *and* allowing the medical practitioners to use their professional training to treat and help patients. The Seventh Circuit's decision disrupts the partnership between the healers and the regulator, and calls into question the legality of compounding by physicians and pharmacists as well as veterinarians, activities for which they all are licensed by their state governments. This raises an issue of vital significance to the public health.

Respectfully submitted,

James R. Phelps
Counsel of Record
Robert A. Dormer
Hyman, Phelps & McNamara, P.C.
1120 G Street, N.W.
Washington, D.C. 20005
(202) 737-5600